

Responsible Opioid Prescribing

A PHYSICIAN'S GUIDE

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Foreword

By James N. Thompson, MD
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Hippocrates' seemingly straightforward directive to "First, do no harm" is anything but simple in today's medical practice. Nowhere is its complexity more evident, and vexing, than in pain management with controlled substances—particularly with opioids.

Patients in pain who rely on opioids for analgesia and improved function deserve access to safe and effective medication; to deprive them of optimal pain-relief certainly does them harm. Yet these same life-restoring medications carry the potential to do grave harm to patients who may be at risk for addiction and abuse. Significant quantities of prescription opioids are diverted into an illegal black market that puts millions of non-medical "recreational" users at risk of addiction and death—many of them young adults and teenagers. Very few physicians are complicit in this criminal diversion, and there are no proven methods for preventing patients from deceptively acquiring prescriptions—pain, after all, is a subjective symptom for which there are no foolproof diagnostic tests. But the fact that some patients will deceive a physician in order to obtain prescription opioids for non-medical use requires us to be vigilant when prescribing these potent and potentially abusable medications.

Physicians cannot single-handedly eliminate the diversion and abuse of prescription opioids. *But we have a solemn responsibility—to our patients and to society—to be vigilant in reducing these risks.* Too few physicians have educated themselves about the simple steps they can take to become more responsible opioid prescribers.

Sadly, many physicians have sought to reduce the risks of opioid prescribing—including the tangible risk to a physician's own licensure if he or she prescribes outside the standards of medical care—by simply not treating patients in pain, or by not treating them with controlled substances. But as pain treatment becomes increasingly intertwined in the larger medical mission of patient care, it's increasingly important for physicians to become sophisticated about the risks and benefits of opioid therapy—the risks of diversion, abuse, and addiction as well as the benefits in managing acute and chronic pain.

Physicians who prescribe opioids are obliged to comply with both state regulations and the federal Controlled Substances Act. In 2005, there were approximately 720,290 Medical Doctors (MDs) and Doctors of Osteopathic Medicine (DOs) registered with the Drug Enforcement Administration (DEA). All physicians should be familiar with the clinical practices that will help them comply with state and federal statutes.

The Federation of State Medical Boards (FSMB) has commissioned this book and is distributing it to physicians to offer clear and concise guidance in managing the risks of pain management with opioids. Incorporating these strategies into your practice will help you fulfill your dual responsibilities to your patients and to your state and federal licensing authorities.

This book grows out an initiative launched a decade ago by the FSMB to create its *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*. These consensus guidelines were formulated with input from the major stakeholders on all sides of the issue, including leading pain and addiction specialists, medical societies, state medical boards, and federal law enforcement agencies including the DEA. These guidelines, which were subsequently updated to a *Model Policy* in 2004, have been praised as “well balanced” by such groups as the Pain and Policy Study Group of the University of Wisconsin.* Twenty-eight state medical boards have adopted the Guidelines or *Model Policy* verbatim as their state guidelines, and ten other states have adopted guidelines with similar language.

The FSMB’s *Model Policy* distills safe opioid prescribing into seven concise principles:

1. Evaluation of the Patient
2. Treatment Plan
3. Informed Consent and Agreement for Treatment
4. Periodic Review
5. Consultation
6. Medical Records
7. Compliance With Controlled Substances Laws and Regulations

Although the *Model Policy* represents the most concise consensus guidelines for safe opioid prescribing, until now this document has not been translated into practical terms for clinical practice. Consequently, few physicians are

* For more information see www.medsch.wisc.edu/painpolicy.

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familiar with these guidelines, and even fewer utilize them in their practice.

This book answers that unmet physician need by explaining how to incorporate the *Model Policy* into your real-life practice. Its author, Scott M. Fishman, MD, is Past President of the American Academy of Pain Medicine and a true thought leader in academic medicine, clinical practice, and public health policy. Dr. Fishman has worked closely with the FSMB on establishing the current *Model Policy* and has been a champion for safe and effective prescribing for pain management.

After reading this book, you'll understand simple steps you can take to comply with state and federal regulations regarding controlled substance prescribing for pain. FSMB's website (www.fsmb.org/pain) will keep this book updated and offers valuable links to state-by-state regulations and other useful websites to help facilitate pharmacovigilant opioid prescribing in your practice.

The term “pharmacovigilance” is one Hippocrates would surely have grasped. It derives from the Greek *pharmakon*, “drug;” and the Latin *vigilare*, “to keep awake and alert, to keep watch.” In modern parlance, it refers to watchfully monitoring and managing the risks of adverse events and side effects of any medication, regardless of the class of drug. Becoming a pharmacovigilant opioid prescriber requires that we understand the risks specific to opioid analgesics and take simple steps to manage them.

Armed with the information in this essential handbook, we can each reaffirm our commitment to “First, do no harm.”

Introduction: Pharmacovigilance and Good Medicine

Over the past decade, two important public health trends have become entwined like the twin serpents in the caduceus: (1) increasing clinical attention across all medical specialties to the undertreatment of pain, and (2) shifting patterns of drug abuse from illicit to prescription drugs—most notably a dramatic rise in diversion and non-medical use of opioid pain medications within the United States. The collision between the War on Pain and the War on Drugs has created a “perfect storm” of controversy. And, for better or worse, physicians are being enlisted to fight on both fronts: combating pain while simultaneously reducing the risk of diversion and abuse of, as well as addiction to, pain medications.

Many of us bristle at adding “pharmacovigilance” and “risk management” to our already lengthy task list. But the combination of potential therapeutic benefit and high risk associated with opioid* analgesics leave us no alternative but to become more sophisticated risk managers. Millions

* The term opioid refers to natural and semi-synthetic derivatives of the opium poppy, as well as similar synthetic compounds that have analgesic or pain relieving properties because of their effects in the central nervous system. These include codeine, morphine, hydromorphone, hydrocodone, oxycodone, methadone, and fentanyl among others. Opioids are often inappropriately referred to as narcotics, a legal term that is no longer used in medicine because it suggests that opioids relieve pain by inducing sedation; while sedation can be a side effect of opioids, it is not the mechanism that produces pain relief.

of legitimate patients rely on these medications for pain relief and functional improvement, so we must include them in our repertoire of potential medication therapies. However, we cannot ignore the potential risks associated with the use of controlled substances, including addiction.

Managing risk is what we physicians do every day with every patient, whether we're considering procedures, medications, or non-medication interventions. Every treatment plan carries potential risks, as does the decision not to treat. Managing risks associated with opioids is fundamentally the same as pharmacovigilance concerning adverse reactions to any class of drugs: essentially following sound principles of medical practice and prescribing and achieving transparency in treatment decisions. The difference with opioids is that these drugs are increasingly diverted or otherwise abused.

Scope of the Problem

A statistical snapshot of prescription drug abuse and diversion in the United States reveals the scope of this alarming public health crisis:

- In 2005 (the latest year for which data are available), more than 10 million Americans were abusing prescription drugs—which is more than the combined number of people abusing cocaine, heroin, hallucinogens, and inhalants.
- The Centers for Disease Control and Prevention report that prescription opioids are now associated with more drug overdose deaths than cocaine and heroin combined: between 1999 and 2002, there was a 91.2 percent increase in the reporting of opioid analgesics on death certificates.¹

- Continuing a decade's long trend, in 2005 more new drug users began abusing pain relievers (2.2 million) than marijuana (2.1 million) or cocaine (872,000). By comparison, in 1990 only an estimated 628,000 people initiated illicit use of pain killers.²
- Data from a set of selected states show that almost 13,000 incidents of prescription controlled substances were diverted by theft from 2000 to 2003. In 2003 alone, 2 million dosages of six opioid analgesics were reported stolen from the supply chain, mainly from retail pharmacies.³

Behind these figures lie millions of individual stories of personal tragedy: untimely death, fractured families, shattered dreams, and wasted lives. Certainly the same spectrum of ills can be found in the wake of any abused drug, but the magnitude of the current problem makes it imperative that physicians become vigilant risk managers who demonstrate transparency in the decisions behind the care they deliver.

Much remains to be learned about the nature of prescription drug abuse in the United States. For example, the exact contribution of prescribers to prescription drug diversion and abuse is not presently known. Because the rise of prescription drug abuse has occurred alongside increased use of opioids in legitimate pain relief, it is tempting to assume cause and effect. However, preliminary evidence does not support this conclusion and more information about how prescription drugs are diverted is crucially needed. If we are to have responsible and effective responses to prescription drug abuse, the problem must be

considered in its full context. To avoid penalizing those with legitimate needs, solutions must factor in the full complexity of drug abuse, addiction and all of the related social and medical disorders. In particular, we must be careful with implications that prescription drug abuse is mostly related to prescribers and their patients, and be careful with implying that limiting medically appropriate use may have significant effects on reversing this disturbing trend.

A Countervailing Need

Concurrent with the epidemic of prescription drug abuse, patients and patient advocates have been pushing to address the equally legitimate cause of undertreated pain. Although these efforts began in the relatively circumscribed spheres of end-of-life care and cancer-related pain, medicine has appropriately widened its perspective to include all debilitating pain that has lost its purpose as an adaptive alarm signal, regardless of the source.

Significant effort has been made to reduce the incidence of untreated or undertreated pain in children, older patients, and in all other vulnerable patient populations. And at least at the level of clinical guidelines, policy statements, and organizational goals, the following general principles are widely accepted:

- Pain management is integral to good medical practice for all patients;
- Opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins;

- Patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient;
- The use of opioids for other than legitimate medical purposes poses a threat to the individual and society; and
- Physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances.

If opioids had no medically redeeming value, the issue of their abuse would be tragic but physicians would have no role to play in minimizing abuse by changing their behaviors or monitoring their actions. The current need for guidance on opioid prescribing arises from the fact that, as addictive and life-destroying as opioids can be for some, they are life-enhancing and non-addictive for others.

Four key factors contribute to the ongoing problem of under-treated pain:

1. Lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment;
2. The perception that prescribing adequate amounts of opioids will result in unnecessary scrutiny by regulatory authorities;
3. Misunderstanding of addiction and dependence; and
4. Lack of understanding of regulatory policies and processes.

To these factors might be added a fifth: the lack of clearly written government regulations and professional guidelines for prescribing, or assistance with how to easily and efficiently incorporate these approaches into the hectic daily practice of physicians.

Filling an Unmet Need

This book is intended to help the responsible clinician understand and implement practices that support rational and transparent opioid prescribing. The following chapters examine each of the seven steps in the FSMB's *Model Policy*:

1. Patient Evaluation
2. Treatment Plan
3. Informed Consent and Agreement for Treatment
4. Periodic Review
5. Referral and Patient Management
6. Documentation
7. Compliance With Controlled Substance Laws and Regulations

Each of these steps, which are only briefly described in the *Model Policy*, are here given an expanded discussion from the perspective of real-world clinical practice. Most physicians already perform many of the key steps recommended in the *Model Policy*. This book focuses on explanations and techniques that specifically address the issues that arise when prescribing opioids. Sometimes this simply means adhering to existing standards of care. At other times—such as in the creation of function-based treatment plans—a significant paradigm shift in perspective will be presented that translates into novel models for creating, monitoring, and modifying treatment goals for your patients in pain.

Prescription drug abuse and undertreated pain are both serious public health crises, but the solution to one need not undermine the other. The least we clinicians can do is make sure that the casualties of this clash are not suffering

patients who legitimately deserve relief. Informed clinicians can take simple steps to ensure that opioids are prescribed safely and transparently—and in the process, those prescribers can justify their decisions should they encounter the scrutiny of regulators.

Regulators and law enforcement agencies, such as the Drug Enforcement Administration, have urged prescribers to be vigilant when prescribing abusable drugs, particularly for patients with known or suspected risk of abuse. Clearly, effective solutions must address the current state of inadequate education that most clinicians receive on safe and effective prescribing of controlled substances. This book is intended as a much-needed step in that direction. Unfortunately, simply knowing the tenets of the FSMB *Model Policy* will not be of value without a basic knowledge of pain, substance abuse, and their treatment. Although this book will not serve this role, other resources are available, many of which are recommended in Appendix A. Moreover, this book will not substitute for maintaining the desire to relieve suffering or the recognition that an important part of mitigating pain is simply being present with your patients and showing them that you care. Although the elements of care described here are critically important for maintaining appropriate delivery of controlled substances, unless you also incorporate the personal part of care, your patients will continue to feel alone and uncared for—and may even resist treatment.

As a physician who specializes in Pain Medicine, I'm optimistic about the future of pain treatment. The confusions and frustrations that currently characterize pain management may simply be the growing pains of a wiser, saner,

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and more uniformly effective patient care approach. Appropriate concerns about the potentially harmful or addictive aspects of opioid medications can be balanced with the equally valid needs of optimal pain relief with adequate risk management. Medicine is all about managing risk while improving health and easing suffering; the safe and effective use of opioids is no different. Opioids are ancient drugs that have been both glorified and demonized in past centuries. It is time we found ways to harness their very real gifts while curbing their very real dangers.

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Chapter 1: Effective Patient Evaluation

“A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.”

—*FSMB Model Policy*

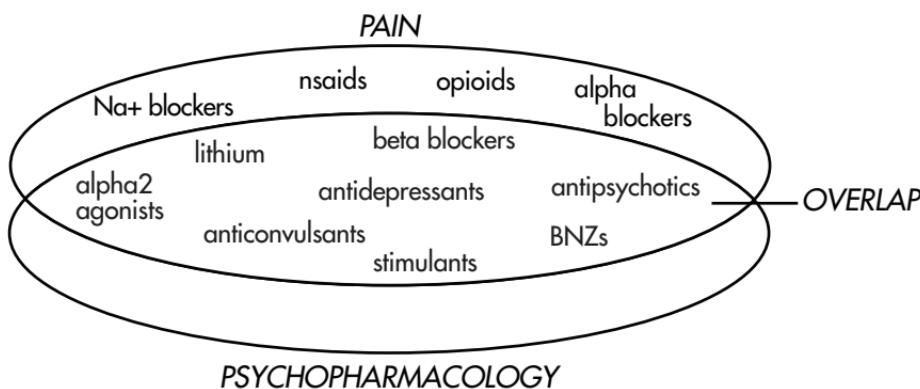
At the core of the requirement to evaluate patients thoroughly is a paradox: although a physician can take a history, do a physical examination, list past treatments, probe for a history of substance abuse, and note coexisting diseases, he or she cannot measure or even confirm the pain that a patient is experiencing. Despite modern diagnostic and evaluative tools, such as MRI, ultrasonography, and electromyography, pain remains an untestable hypothesis. Perhaps one reason that physicians are reluctant to aggressively treat pain has to do with the often frustrating fact that we can't prove that someone is or is not in pain, just as we can't prove the presence or absence of pain relief. However real pain is to a patient, it remains subjective to

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the physician. As Elaine Scarry notes in her book *The Body in Pain*: “To hear about pain is to have doubt; to experience pain is to have certainty.” In the end, physicians must accept the maxim “Pain is what a patient says it is.” Anyone complaining of pain is suffering from something; the physician’s job is to try to figure out the cause of the suffering and to formulate a plan for reducing it.

Today it is widely recognized that pain is never simply “physical” or “psychological.” The mind is *always* involved in a patient’s experience of pain, and it can magnify or diminish pain perception. The almost complete overlap between the medication groups used by both psychiatrists and pain specialists attests to the inextricable links between mind and body that make meaningless the cliché phrase “the pain is all in your head.” (See the graphic below.)

The Overlap of Major Drug Groups Used in Pain Medicine and Psychiatry



Pain measurement scales, such as the familiar 0 to 10 numerical pain scale or the “faces” pain rating scale, can provide some degree of guidance about a patient’s experience of pain intensity, but all are open to wide variations among subjects experiencing similar problems, and within a subject at different times. Multidimensional instruments, such as the McGill Pain Questionnaire or the Brief Pain Inventory, provide a broader picture of a patient’s experience, but are usually more cumbersome to administer in a busy clinic setting and, in the end, suffer the same limitations as all other attempts to measure pain.

The best way to begin assessing a patient’s pain is to ask about it and listen. This may sound trivial, but, in the hurly-burly of daily clinical life, it is essential. All too often physicians become overly focused on quantifying, categorizing, and deciding how best to treat pain as a single symptom. In the process, they may not ask pertinent questions that relate to their patients’ global experience of suffering, and they ultimately distance themselves from their patients. In focusing narrowly on a disease or symptom, physicians can lose the “big picture” of the whole person and thus miss important diagnostic clues that could lead to more effective interventions.

Three relatively simple steps can vastly improve taking a history from a patient in pain:

- Take control of time;
- Focus on the patient, not the pain; and
- Use reflective listening skills.

These steps can reconnect the clinician with the patient, improve the efficacy of analgesic treatments, and increase personal satisfaction.

Step 1: Take Control of Time

In some ways, this suggestion may be largely outside our control. Physicians are increasingly pressured to see more and more patients. The average patient in pain, particularly those in chronic pain, typically has a complex presentation and histories. Clinicians must be relentlessly thorough, looking under every “rock” for clues. And being a clinical professional means we withhold judgment until we have ample evidence. This is an unavoidably time-consuming process. Thus, a patient in pain is almost automatically a “difficult case.”

Unfortunately, these challenges can lead clinicians in exactly the wrong direction. Instead of allotting increased time and patience to the diagnostic task, physicians confronted with “difficult” patients may *speed up* and, either consciously or unconsciously, rush to judgment in an effort to minimize time spent with an emotionally sensitive, demanding, or frustrated patient. Full adherence to the Evaluation component of the FSMB *Model Policy*, in other words, requires a commitment to spending enough time and attention to what the patient is saying both verbally and through behaviors.

Step 2: Focus on the Patient, Not the Pain

In taking a history about pain, physicians should ask questions not only about the pain itself (its location, intensity, duration, etc.), but also about the pain’s collateral damage to the patient’s life. To use a musical metaphor, you need to listen not just to the lyrics (the self-evident parts of what the patient says), but to the music as well (the less obvious verbal and nonverbal messages about their feelings, fears,

expectations, goals, etc.). Clinicians need to be alert to subtle warning signs of trouble and take the time to ask follow-up questions.

Pain is usually interwoven with unpleasant experiences, such as fatigue, nausea, depression, and anxiety, among others. These are absolutely vital connections for a diagnostician—if you miss them, you'll miss understanding the true dimensions of a patient's pain and possibly some of the most useful avenues for alleviating his or her suffering. For example, depression can dramatically alter pain perception—almost always for the worse. Patients may not offer unprompted information about their depression out of fear that the physician will think their pain is “all in their head.” If you don't ask direct questions related to mood, or pick up on the subtle signs from the patient's answers that suggest psychosocial deterioration, you may not recognize this significant factor in the experience of pain. Similarly, many other aspects of a person's life can affect his or her pain, such as the use or abuse of licit or illicit drugs, high stress levels at work or home, or physical deconditioning because of a lack of activity.

Step 3: Use Reflective Listening Skills

Patients in chronic pain are frequently more emotional than they might be otherwise. Pain undermines our ability to cope with the ups and downs of normal life. Pain can make any of us defensive, short-tempered, or even hostile. Not only are these patients experiencing pain but, by the time they see you, they may have undergone previous treatments that either were ineffective or exacerbated their symptoms. In some cases, the tension may be

palpable and, in others, it may simply be suppressed. It must be emphasized that above all, the patient in pain wants and needs to be believed and validated. In a sense, then, treatment actually begins during the process of assessment.

An effective strategy for collecting a comprehensive history and building a successful patient-physician relationship is *reflective listening*. This means listening carefully and non-judgmentally to what your patient is saying, then reflecting it back in a slightly modified or reframed manner. Aside from allowing the clinician to confirm the accuracy of their beliefs, this gives the patients both the indication that they are being heard and a chance to correct mistaken beliefs or perceptions that could affect their care.

Using a reflective listening strategy may be easier said than done. If a patient says something at odds with the evidence, or uses threatening or hostile language, one's natural reaction is to immediately defend oneself, rebut the charges, or deny the underlying assumptions. This can quickly create confrontation or a power struggle that can be difficult to overcome. It is much more effective to take a moment before responding, and then to consciously try to simply restate what the patient just said. For example, a patient may angrily say "Doctor, those pills you gave me don't work—I told you before that I need something stronger." Even in cases where you suspect the patient may be angling for stronger and possibly riskier medications for spurious reasons, a directly confrontational approach would probably be ineffective. A better response might be something like "You seem to be irritated with me because you don't think the medications I

prescribed are working for you.” Reflective listening responses such as this provide several advantages:

- They are less likely to evoke or exacerbate patient defensiveness;
- They encourage the patient to keep talking and reveal more about his or her true motives;
- They communicate respect, caring, and compassion, and encourage a therapeutic alliance; and
- They open an opportunity for the patient to correct misunderstandings or clarify exactly what he or she means.

Although reflective listening can be particularly helpful when a patient is emotional, it is a useful approach for following up on or probing answers to questions that you ask during any patient encounter.

Elements of a Comprehensive History

Comprehensive evaluation of a patient in pain usually requires moving beyond the typical list of questions asked during a general history. In most cases where pain is the chief complaint, it is certainly appropriate to begin a conversation by asking about the pain, but then it is usually advantageous to move on to the broader context and impact of that pain. Here are some points that may be useful to cover in an initial evaluation:

- Location of pain
- Character of pain (i.e., shooting or stinging, continuous or intermittent, worse at night or in the morning)
- Lowest and highest pain on 0 to 10 scale in a typical day
- Usual pain on 0 to 10 scale on a typical day (anchored by verbal descriptors)
- How and when pain started

- Exacerbating and relieving factors (i.e., stress, alcohol, other medical concerns)
- Effect of pain on sleep
- Effect of pain on mood
- Effect of pain on functioning at work
- Effect of pain on quality of personal life, such as relationships, sex, or recreation
- Is the patient involved in a legal or protracted insurance process connected to his or her chronic pain, such as a motor vehicle accident or disability case?
- What does the patient expect from medications or other treatments in terms of analgesia or recovered function?

In the course of your conversations with patients, be alert to signs that they are minimizing their pain. Although it may seem counterintuitive, some patients fail to convey the true nature and severity of their pain, which can, albeit unintentionally, undermine the effectiveness of their treatment. They may not want to disappoint their physicians or offer a distraction from treating their primary disease; they may think they should just “suck it up” and endure their pain; they may think pain is inevitable with their illness; or they may want to avoid acknowledging that their disease is progressing. Some may worry that if they mention their pain, their doctor will see them as complainers or even as drug-seekers or addicts. Many people also under-report pain because they fear that pain medications will dull their cognitive abilities, lead to addiction, or result in unmanageable side effects. And last, some patients may believe that there is value in suffering, it is their due, or that in some way they deserve to be in pain to expiate some form of “wrong-doing” or “sinfulness.”

If you suspect a patient is minimizing his or her pain, reflective listening can help the patient see what you see and allow you to probe for the reasons underlying the minimizing. At some point, you might scratch your head and say "I wonder if you are the silent sufferer type?" Very few are offended by being described as "stoic," which is usually considered something of a compliment to many patients. Being seen as someone who is doing his or her part to bear the suffering is usually consoling. Regardless of the reasons for minimizing, this approach can help you take a history by allowing patients to feel that they will not be judged negatively and can speak freely and candidly about their pain.

Screening Patients for the Possibility of Addiction or Drug Abuse

All patients complaining of pain are suffering from something and deserve a physician's empathy and compassion. But a small minority of people seeking treatment may not be reliable or trustworthy. The problem for the clinician at the front line of medicine is not that such patients are bad people who are committing sins; it is that the help that such patients are asking for will not remedy their problem and may be harmful to themselves and others. This approach evokes the professional responsibility to first do no harm. It is based solely on risk management that requires you to maintain constant vigilance without impulsively rushing to judgment. This is not unusual for physicians. For instance, there is an old adage that if you don't suspect a pulmonary embolism, you'll never catch one. The same level of suspicion (without judgment)

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applies to the assessment of the patient in pain. If you do not suspect the pain may be caused by a nerve injury, you may never catch neuropathic pain. If you don't suspect the possibility that someone who asks for an opioid by its brand name might have a problem with drug abuse, you may miss a valuable opportunity to help the patient.

On the other hand, allowing suspicions to foster judgmental conclusions may be equally harmful to the patient and society. A physician must, therefore, maintain a discreet but keen vigilance for potential harm from any treatment. In the case of treatments that include controlled substances, this must include the potential for deception and abuse.

Although it may sound contradictory to exhort physicians to be empathic and supportive while simultaneously probing aggressively in search of the truth (including information that the patient may not want to reveal), this is not such a difficult balance to achieve in daily practice. You can maintain a tolerant, nonjudgmental, and concerned posture yet remain persistent in your quest for the valid information required for prudent decision making.

Whenever a clinician considers treating pain with a controlled substance, such as an opioid, risk of abuse or diversion is always a possibility, no matter how remote, and must be assessed. Exactly who to suspect and when to be proactive in investigating risk factors is an area of great debate. To date, no convincing data exist to support the strategy of focusing on any one specific population or setting—which means that physicians must be vigilant with all their patients. The term “universal precautions” has been applied to this approach and, in pain care, assumes

that any patient in pain could have a drug abuse problem—just as any patient requiring a blood draw for a simple lab test could have HIV. Gourlay and Heit (2006) argue that “since there is no one behavior that is [diagnostic] of a substance use disorder, and since the prevalence of addiction in the general population is not insignificant, it is prudent to thoroughly inquire into substance use in all patients, not only those who are being treated with the opioid class of drugs. Failure to do so may leave a potentially treatable condition, such as addiction, undiagnosed and untreated.”¹

Treating everyone with the same screens, diagnostic tests, and administrative procedures can be viewed from one angle as an attempt to remove bias and essentially level the playing field so everyone is treated equally and screened thoroughly. It also could be perceived as undermining the patient-physician relationship. Despite defensible efforts to be as consistent as possible to all, as well as to cast the broadest possible surveillance, some patients or clinicians may see the universal precautions approach as a sign of distrust or evidence that the patient is being presumed guilty until proven innocent. Dealing with this may require clear education for patients as to why such procedures and practices are necessary and in their best interest.

For the actual assessment of a patient’s risk of having a substance abuse problem, several tools have been developed but, to date, no single tool has been widely endorsed or thoroughly validated. CAGE is a classic rapid screen developed for alcohol abuse that can easily be modified for any abusable drug. This brief questionnaire (which can be

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incorporated into a self-administered written assessment form) asks whether a patient has ever:

C: Wanted or needed to Cut down on drinking or drug use?

A: Been Annoyed or Angered by others complaining about the patient's drinking or drug use?

G: Felt Guilty about the consequences of the patient's drinking or drug use?

E: Taken a drink in the morning as an "Eye opener" to decrease hangover or withdrawal?

A single positive response suggests that the clinical decision to prescribe opioids to the patient must be considered in relation to a potential for abuse and addiction. It does not mean that opioid use will become problematic or that opioids are contraindicated, just that you should carefully determine if the therapeutic benefits of prescribing an abusable drug is in the patient's best interest. If you deem a controlled substance is appropriate, you must exercise particular care in crafting your patient-physician agreement (whether verbal or written) and your risk management plan for monitoring and follow-up.

Many other tools exist to help screen for addiction or abuse and are listed in Appendix A. However, no one tool will be entirely reliable and the astute clinician will recognize that the signs of abuse or addiction may not be readily or immediately apparent in the typical clinical setting. If suspicion is raised for a given patient, information about previous problems with substance abuse may be obtained from a collateral source, such as a family member, friend, or other health care professional. Treatment is not required to commence until the physician is comfortable with the integrity of the situation. Understanding the signs and

symptoms of abuse or addiction will help guide questions. Feeling rushed to make a prescribing decision may in itself reflect a clinical problem (not related to the issue of abuse or addiction) that is worthy of review and discussion with the patient.

Necessity of a Comprehensive Physical Examination

Although Medicare and other institutions have defined what constitutes a physical examination for purposes of coding and reimbursement, exactly what comprises an appropriate or acceptable physical examination for pain is not well-defined, largely because it will differ from case to case. Regulators who expect to see a physical examination as part of the evaluation that leads to appropriate pain care involving controlled substances assume that a basic, if not focused, examination is warranted. The exact components of the examination are left to the judgment of the clinician who is expected to have performed an examination proportionate to the diagnosis that justifies a treatment.

For instance, it might be expected that a patient treated with opioids for chronic low back pain will have at least received a basic examination of the lumbar spine. Such an examination might reveal pathology that could be amenable to other treatments, perhaps some with less risk. Even if the physical exam does not offer clues in the case of some pain disorders, this cannot be confirmed until an examination is completed. Unless due diligence is evident with a documented physical examination, a physician's decision to begin a treatment that carries risk may be questioned.

Exceptions

It's not always possible to obtain a thorough history or evaluation for a patient. In the emergency department, the operating room, at night or on weekends, a physician or surgeon may not always be able to verify the patient's history and past medical treatment. In such circumstances, physicians must balance the need for vigilance about potential addiction or diversion with the need to treat the patient's pain. As with most treatment decisions, an approach based on risk versus benefit must determine the appropriate response. Physicians are commonly faced with risks associated with treating as well as with withholding treatment. Too often, it is impossible to know which risks are more likely and the clinician must choose to either avoid suffering and treat, accepting the potential risk for abuse or choose to prevent potential abuse and not treat, accepting the risk that the patient might suffer unnecessarily. Such decisions must be based on the long-term impact of the treatment, its duration, and the potential for diagnosing an adverse outcome were it to occur. For example, it would be acceptable practice in the case of a complaint of pain in the ER to prescribe small amounts of an opioid analgesic that would get the patient through to the following day until a clinician with a longitudinal relationship with the patient is available to follow up. The potential harm from undertreated pain, weighed against the limited potential harm of a few opioid pills, may support this determination.

Assessing Risk and Benefit

Physicians must routinely balance the potential risks and benefits of any treatment plan. But in the face of the com-

plexity of pain, as well as the specter of scrutiny from healthcare regulators and law enforcement, it's easy to become paralyzed and decide that the least risky course is to not treat the pain aggressively or at all. But doing nothing can be the riskiest decision of all. For example, consider the case of a 76-year-old woman who comes into an emergency room with rib fractures. Adequately treating her pain is not just a matter of relieving her immediate physical problem: inadequate lung inflation and efforts to suppress coughing because of pain increase her risk of pneumonia and death. While most cases aren't this clear or dramatic, ongoing pain erodes quality of life and slowly deconditions a person's physical, emotional, and spiritual well-being. Both directly (via inappropriate activation of stress-related hormones) and indirectly (by inducing inactivity, insomnia, anxiety, or depression), pain compromises the body's defenses and leaves sufferers vulnerable. Uncontrolled chronic pain also undermines the management of any pre-existing chronic condition, such as diabetes, cardiovascular disease, and psychiatric conditions such as anxiety or depressive disorders. Chronic pain in combination with depression increases the risk of suicide.

Looking at the complete landscape of pain and its collateral damage, it is clear that the decision whether or not to treat pain offers physicians no risk-free option. If the risk to the patient associated with a given treatment outweighs the risk of withholding that treatment, then other less risky treatments must be considered. Although physicians should not feel compelled to use any treatment modality (including opioid analgesics), the risk of non-treatment must always be factored into any pain management

decision; not treating pain is often not a “safe” option. This may seem obvious, but physicians face patients in pain each day and choose what they perceive as the lesser of evils: less treatment as a means to avoid “risk.”

Another risk posed by nontreatment or undertreatment of pain affects the physician, but not the patient directly. Physicians have been successfully sued for not treating pain aggressively. For example, the 2001 *Bergman vs. Eden Medical Center* case involved a physician who was found guilty of “elder abuse” arising from alleged under-prescribing of pain medication. This jury brought a \$1.5 million verdict against this physician, and the jury was a single vote away from levying fines for much higher damages. This case led the California legislature to pass a law requiring the Medical Board to publicly declare its policies on how it investigates physicians in pain cases and requiring all California physicians to have mandatory continuing medical education on pain and end-of-life care. A more recent California case, in which a physician was accused of elder abuse for under-treating pain, was settled just prior to the start of the trial for an undisclosed sum. In this case, the Medical Board formally and publicly sanctioned the physician for undertreatment of pain. Even though such cases represent rather extreme situations, these legal precedents sound a warning that there are risks associated with under-treating.

This does not imply, however, that all patients must be treated aggressively with opioids or any specific treatment. It simply means that all patients complaining of pain deserve adequate assessment and treatment based on consideration of risks and benefits to the patient. When trans-

parent documentation provides the rationale for treatment decisions, physicians should feel comfortable that they have done their best to provide appropriate patient care while meeting their fiduciary obligations as “officers of the public health.”

Summary

This chapter has reviewed the key elements of effective patient evaluation. Despite modern diagnostic and evaluative tools, pain remains an untestable hypothesis. Nonetheless, the evaluation and history taking of patients in pain can be improved by: taking control of your time; focusing on the patient, not the pain; and using reflective listening skills. Be alert to any signs that a patient may be minimizing his or her pain. And when considering use of a controlled substance in pain treatment, take a substance abuse history, and as in any therapeutic intervention, pay close attention to the risk management plan. In doing so, the risks involved in not treating must always be factored into any pain management decision; not treating pain is often not a “safe” option.

References

1. Gourlay, D., and H. Heit. Universal precautions: a matter of mutual trust and responsibility. *Pain Medicine*, Mar.-Apr. 2006, 7(2):210-211, author reply 212.

Chapter 2: Creating a Treatment Plan

“The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.”

—*FSMB Model Policy*

Because measuring pain is fundamentally an untestable hypothesis, the use of subjective reports of pain relief as the sole outcome of treatment will be difficult to measure objectively. Indeed, the very notion and practice of “pain relief” often contains a hidden assumption: that it’s possible and desirable to “relieve” pain completely. Everyone lives at certain times with varying degrees of physical and/or emotional pain or discomfort. People also differ significantly in their pain tolerance and have individual thresholds at which pain impairs function. The rare cases of people with a congenital inability to feel pain demonstrates (usually tragically) the profound disadvantages of a life with “zero pain.”

Ironically, the traditional 0 to 10 pain scale used so often in clinical care perpetuates this misconception: that the ideal or attainable condition is “zero pain.” It’s a small step from this subtle assumption for doctors (and their patients) to assume that the goal of pain treatment is the *elimination* of pain. This chapter will review some of the pitfalls of this approach. Even the primary goal of pain *reduction* may miss an essential point: the direct sensation associated with pain is not the only important variable associated with a patients complaint of pain and may not be the most important feature of the overall presentation. A critically important part of understanding pain, as a means of formulating an effective treatment plan, is to look beyond the pain sensations themselves to how those sensations are affecting and possibly eroding a patient’s quality of life. Specifically, how is pain affecting the patient’s functioning in daily life?

From Analgesia to Functioning: A Necessary Paradigm Shift

Since pain impacts all domains of a patients’ life, complete evaluation of pain involves looking into the *effects* that these noxious signals are having on physical and psychosocial functioning. This knowledge is critically important for creating the solid treatment decisions and management plan envisioned in the *Model Policy*. Shifting from analgesia alone (or uni-dimensional pain intensity scores) to a function-based paradigm offers the following tangible advantages:

- Treatment goals become more objective and verifiable (not relying on subjective reports alone);
- Individual differences among patients, both in terms of pain tolerance and functional goals, are respected;

- An individualized evidence base is created for making appropriate risk/benefit decisions on pain treatment options; and
- Prescribing decisions (including decisions to wean a patient from a drug regimen) are tied to multidimensional outcomes, many of which may be objectively demonstrable to the clinicians and the patient.

Most important, a function-based treatment strategy offers the promise of increasing your patients' quality of life and subsequently decreasing the burden of their pain. Under normal circumstances, pain is an alarm that warns us of impending or actual harm. It is designed to grab our attention, and when pain is severe enough, to make it impossible to attend to anything else. Thus, when the alarm itself is injured or malfunctioning, pain does not turn off normally and the constant drain on attention undermines the affected individual's ability to attend to the other aspects of his or her life—often aspects that make life worth living. Chronic pain intrinsically diminishes one's capacity to function and subsequently erodes the basic elements of daily life, such as physical activity, concentration, emotional stability, interpersonal relationships, and sleep. This can, in turn, degrade role function, such as at work or home, leading to depression, anxiety, and insomnia, among other comorbidities. While significant pain worsens function, relieving pain should reverse that effect and improve function. Simply "feeling better," without improving functioning in some aspect of an individual's life, may reflect an inadequate outcome. The most successful chronic pain management includes regaining collateral losses associated with that pain.

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This is a paradigm shift for many physicians, most of whom have been trained to focus almost exclusively on pain sensation and intensity—believing that the sole outcome is to reduce or eliminate a patient's intensity rating. But reducing a patient's pain score from, say, 9 to 3 is only one piece of a much larger puzzle. Particularly when treating chronic conditions for indefinite periods, it is not enough that patients say they “feel better.” Depending only on such a purely subjective outcome can easily lead a physician to overlook evidence that a medication is ineffective or is producing side effects that may be reducing the patient's quality of life. In some cases, pain relief may occur without significant functional gains but on more thorough assessment, function may be found to have deteriorated. The possible reasons for this are many, including side effects, use of analgesic medications for secondary purposes such as sleep or anxiety rather than pain, or even frank abuse or addiction. Even if a medication is effective for a certain symptom, its side effects may present risks that outweigh benefits. A broad perspective and a comprehensive history are required in order to assimilate the salient facts that inform more carefully reasoned treatment decisions. Reliance solely on patient self-reporting also, of course, makes it easier for patients to deceive clinicians and themselves about their treatment outcomes, including when problems relate to drug abuse.

Setting Functional Goals

Evaluating treatment effectiveness by linking pain relief to functional gain makes many physicians uneasy. It is understandably difficult to subjugate a patient's positive subjective report of improvements in pain intensity to objective evi-

dence that functional gains have or have not been achieved—or, worse, that actual harm is taking place. But analogous situations are frequently encountered in other realms of medicine. For example, if a diabetic also has problems with chronic vasculitis, corticosteroids may effectively ease some of his or her symptoms. But corticosteroids, amongst other risks, worsen glucose control with serious consequences in a diabetic. Diabetic patients who would argue that they should be chronically maintained on corticosteroids because it is the only way they feel well challenges the physician who must make a rational clinical decision in the context of the severe toxicity of chronic corticosteroids in diabetes. No reputable physician would normally accommodate such a request except under highly select circumstances (e.g., end-of-life care where comfort is the principle goal of treatment). Most would clearly recognize that the risks outweigh the benefits. The physician is forced to say, “I’m sorry, but I can’t give you this medication even though it makes you feel better because it’s going to harm you in the long run.” A patient who continues using an opioid medication, but whose quality of life is either unchanged or actually worsens, may well be in the same boat—and our response as physicians must be the same: “This treatment is not working well because . . . We can do better so let’s find a more effective way to both control your pain and improve the quality of your day-to-day life (or help you become more functional).”

As illustrated by the case example below, some patients may report large changes in their pain score even as their quality of life erodes.

Contrast this case with the patient who reports that her pain dropped from 8 to 6 but is no longer bed bound, is

Case Study

Mike was a 38-year-old construction worker with lumbar disc injury. After laminectomy and fusion surgery, the expected bone regrowth didn't occur and the fusion surgery was repeated. This fusion appeared to work, but his pain continued. Several nerve block procedures failed to bring relief.

After several housebound months, Mike sought help at a nearby pain center. He lacked energy, slept through each night in his reclining lounge chair, and was often irritable and short-tempered with his wife and children. He complained that the hydrocodone he was prescribed wasn't working anymore. His wife reported that Mike had used various drugs in the past and currently used both alcohol and cannabis.

His physician negotiated a realistic function-based treatment plan for Mike. His initial goals were to sleep in his bed again, attend a function at his son's elementary school, enroll in a pain education class, and begin a program of gentle but long term physical therapy. Four weeks later Mike had titrated up his opioid dose as prescribed. "The medication is really working doc," Mike said. "My pain's gone from an 8 to a 2 most of the time."

But under questioning it became clear that Mike had not actually made progress. He was still sleeping in the lounge chair. He missed the school science fair. He had only seen the physical therapist once. He also wasn't sleeping well . . . even though he felt sleepy most of the time.

The physician realized that the sedation he was experiencing was interfering with his progress toward functional goals.

After considerable patient education and negotiation, Mike agreed to taper off the opioid and try a new regimen of a non-amphetamine stimulant in the morning and a sedating medication for the evening. This normalized his sleep/wake cycles and left him with more energy during the day. He used non-opioid analgesics for his pain.

Four weeks later, Mike had attended five meetings of a chronic pain support group, and several sessions with a pain psychologist who taught him skills for coping, distraction, and relaxation. His wife reported that he had been regularly attending physical therapy. Twelve weeks later Mike looked relaxed and alert. His pain was not gone; he said it varied from about a 3 to a 5 (out of 10) from day to day. But he said he could live with that. He was moving around, making slow but steady progress in physical therapy, and becoming socially active. He was benefiting from a positive feedback loop: a relatively minor reduction in his pain led to improvements in function. This, in turn, further reduced the importance of pain in his life, which further increased his function.

able to bathe herself again, and is starting to engage in small amounts of exercise. Clearly this is an example where the patient with the greater reduction in pain score should be viewed as a treatment failure and the patient with the more modest pain score reduction is a treatment success. A 20-percent reduction in a pain score (i.e., two points on the standard pain scale) may not seem significant, but it is a perfectly acceptable goal when it produces significant benefits for a patient, as illustrated in the chart below.

Activities Impaired by Increasing Pain Severity*					
				Relate	
			Walk	Walk	
		Sleep	Sleep	Sleep	
	Active	Active	Active	Active	
	Mood	Mood	Mood	Mood	
Work	Work	Work	Work	Work	
Enjoy	Enjoy	Enjoy	Enjoy	Enjoy	Enjoy
3	4	5	6	7	8
>>>>>>>>> Worst Pain Rating >>>>>>>>>>					
* Assessed in cancer pain patients					
Source: Cleland, C.S., and K.M. Ryan, <i>Ann. Acad. Med. Singapore</i> , 1994,23:129-138.					

The illustration reflects the typical 0 to 10 pain scale as it impacts function at scores ranging from 3 to 8. It clearly shows how function is progressively impaired as the pain rating increases, and conversely, how seemingly modest reductions in pain can translate into dramatic functional improvements as pain ratings are reduced. A patient told that a specific treatment will reduce his or her pain by 20

percent may be unimpressed by this goal. In some cases of chronic pain, the spiraling loss of function may be a paramount concern, and halting a pattern of progressive loss of function and other losses related to pain may become a functional goal in itself.

A single pain score may be important to patients as they may have learned through other medical experiences that it is important to their clinicians as a quantitative yardstick with which to effectively communicate with their health care providers. But pain is so subjective that a single value on a single visit may have much less utility than pain scores used to help monitor changes over time. If the treatment outcome is framed, instead, in terms of the reclaimed function through a few-point reduction on the pain scale, they may be much more likely to see this as a major positive outcome and commit to this treatment goal. Reductions in pain scores are nonetheless important and must be honored and incorporated. Subjective pain relief is valuable and desirable. However it is a potential problem when subjective pain relief is used in isolation and as a sole determinant of treatment outcomes for a chronic condition. In chronic pain management, it is often best used as part of the primary treatment outcome with the overarching goal of functional improvement.

Function and Controlled Substances

Switching to a function-based paradigm for creating treatment plans has particular value in the area of controlled substances, because function offers a useful way to differentiate a patient who is truly addicted from one who has a similar appearance but is not. This differentiation is

grounded on the fact that addiction (as well as pain) leads to dysfunction while pain relief should improve function. When given adequate pain relief, persons in chronic pain can gain or maintain function in their lives. Addiction, on the other hand, involves drug use that causes dysfunction in one or more spheres of a person's life. Addicts have a disease that impairs their ability to control or modulate their use of a drug despite the dysfunction and harm that it incurs. In the setting of active addiction, function does *not* improve with exposure to the drug. Although many cases where analgesic trials do not lead to functional improvement are caused by something other than addiction or abuse, the lack of functional improvement always indicates a problem with the treatment or some other facet of the patient's life that deserves attention. At the very least, in cases where analgesic trials do not lead to functional improvement, re-evaluation should occur, utilizing a differential diagnosis that considers substance misuse, diversion, abuse, or addiction.

A lack of function or dysfunction that is manifest in a treatment program may turn out to have its roots in function-limiting side effects, such as sedation, or may be caused by untreated affective disorders that are commonly associated with chronic pain. However, sometimes the manifestation of dysfunction will represent addiction, diversion, or abuse, a distinction that may be difficult to make without objective measures. Putting functional goals at the heart of a treatment plan, in other words, can shed valuable light on the sometimes confusing presentations of patients in pain. (The subject of addiction versus pseudoaddiction is covered in more detail in Chapter 4.)

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As mentioned in the previous chapter, the phrase “universal precautions” has been borrowed from the field of infectious diseases. The term refers to a standardized approach to the assessment and ongoing management of *all* patients with pain. Just as it is impossible to predict if patients (or their body fluids) will harbor an infectious agent, it’s impossible to predict with any degree of certainty which patients in pain will abuse prescription medications. Using standardized assessments and approaches for *all* patients, such as written agreements, random drug screening, or screening instruments for risk of abuse, makes it possible to offer a broader safety net that avoids potential disparities in care, helps meet requirements for informed consent, improves patient education and participation, and minimizes overall risk. If logistical or financial constraints limit the ability to pursue this broad strategy, an alternative is to apply randomized screening only on high risk patients or patients exhibiting aberrant behavior. However, since we are not adept at determining who is and is not at risk for opioid abuse, such approaches have risk for stigmatizing patients and potentially creating disparities in care.

Getting Started

You don’t need expensive interventions or high-tech diagnostics to embark on a function-based treatment plan. All you need is a pen, paper, and the information you’ve gleaned from a basic conversation with your patient. The functional goals of a treatment plan must be achievable and realistic. Progress is usually slow and gains are made one step at a time. In the case of chronic illness marked by

longstanding deconditioning, recovery requires reconditioning that may take weeks or months. Patients should be educated about this need for reconditioning and it must be stressed that the process is a marathon, not a sprint. Experience shows that if a patient can achieve one goal, his or her motivation and attitude improve, making the next goal that much easier to achieve. As with other life pursuits, “The key to success is success.”

Here, for example, is how a set of functional goals could be set up for “Mike,” the construction worker featured in the case study earlier in this chapter. Although Mike was focused exclusively on his pain and need for relief, the larger goal for any physician (after sufficient medical evaluation for a treatable lesion) should be to find a strategy that would improve his activity level, restore his self-esteem, and rebuild his quality of life. Often the best place to start is with a simple yet important question: “What is it that you’re going to do on this medicine (or treatment) that you can’t do now?” Sometimes patients won’t know how to answer at first because they are unused to thinking in terms of functional goals. They might say, “I don’t know . . . I just want to feel better, that’s all.”

As just explained, this is an understandable response, but it does not help to develop a set of realistic functional goals and some “hard” measures by which to evaluate outcomes. For example, upon further questioning Mike might want to sleep in his bed again instead of the reclining chair, attend a function at his son’s elementary school, attend a pain education class, and begin a program of gentle but long-term physical therapy. He might agree to bring records from his class and physical therapy sessions and

have his wife confirm his progress in the other areas. Both physician and patient would now have the start of a road map by which to measure progress, and the physician would have evidence on which to base treatment decisions.

This approach also lays the foundation for making decisions about changing the course of, or even terminating treatment in cases where goals are not met, adverse effects outweigh benefits, or in rare cases where a person is knowingly deceiving a physician to procure opioids for illicit purposes. For persons who intend to abuse drugs that are being prescribed to them, participating in a program with expectations for objective functional outcomes will present a sizeable barrier. Many such individuals may seek care elsewhere rather than undertake the effort of participating in a functional outcomes charade.

Components of an Effective Treatment Plan

A function-based treatment paradigm offers both the clinician and patient many benefits that can liberate a treatment course from the often murky terrain of chronic pain management. As you integrate this approach into your practice, keep these principles in mind:

- Elimination of all pain (i.e., “zero” pain) is usually neither possible nor desirable;
- A patient’s pain score is just one of many variables related to overall status and potential for recovery;
- Treatment goals should not be set *primarily* in the form of changes in pain scores;
- Seemingly insignificant pain-score reductions may actually be extremely significant in terms of reclaimed function;

- Functional goals must be set collaboratively between patient and doctor, be realistic and achievable, be meaningful to the patient, and be verifiable;
- Functional goals must be revisited and recalibrated at regular intervals by both doctor and patient; and
- Because patient values and the functions they desire in life vary, each patient will have a unique set of functional treatment endpoints.

Although using functional outcomes may add some work to the start of a treatment plan, it will pay dividends over time. As noted above, a functional plan need not be onerous, complex, or elusive. On the contrary, a commonsense and individualized approach should result from asking simple questions, respecting the patient's values, and targeting goals of importance to the patient, starting with the most attainable and progressing over time to greater challenges. Goals must be periodically followed up and outcomes assessed, using the results to determine the direction of future care. At some point, patients may plateau at a certain level of function and each clinician, in consultation with the patient, will have to use their clinical judgment to determine whether this is acceptable or changes are needed. Even after a plateau has been reached in which stable medications are offset by stable function at an acceptable level, ongoing periodic review with follow-up functional assessments are necessary to be able to detect any decline or improvements that may occur over time.

Summary

Chapter 2 explored how to create effective treatment plans for patients in pain. In formulating a plan, targeting direct

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sensations associated with pain are not the only important feature to focus on. Complete evaluation and planning means looking beyond the pain signals to the effects that those signals have on physical and psychosocial functioning. Optimal outcomes include “feeling better,” but are best objectified with improved functioning in some or multiple aspects of an individual’s life. Switching to a function-based paradigm offers a useful way to differentiate a patient who is succeeding with an analgesic treatment from someone who is not and may even be abusing, diverting, or addicted. Attention should be paid to even small reductions in the pain score, since they may be extremely significant in terms of reclaimed function. Sustained success will require that functional goals are revisited and recalibrated at regular intervals by both doctor and patient.

Chapter 3: Informed Consent and Agreements

“The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient’s surrogate or guardian if the patient is without medical decision-making capacity. The patient should receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including: urine/serum medication levels screening when requested; number and frequency of all prescription refills; and reasons for which drug therapy may be discontinued (e.g., violation of agreement).”

—*FSMB Model Policy*

Like all treatments, effectively treating pain requires a plan that will often hinge on a careful bilateral negotiation with the patient. In medicine, any treatment plan should constitute an implied agreement between a physician and a patient. Formalizing a treatment plan by putting it in writing can serve many helpful purposes, not least of which is obtaining and documenting informed consent. (The general subject of documentation will be covered more thoroughly in Chapter 6.) A written patient-physician

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agreement can serve to achieve a complete and uniform process, as well as help deal with any potential curves or bumps that may occur along the road. Such an agreement, often termed a patient care contract, can cover many different facets of care ranging from risk/benefit assessment and informed consent to administrative policies or any other educational issues that the clinician believes should be emphasized. Written agreements can also improve the coordination of care among a team of healthcare providers when they all are required to sign the agreement. (The articles in the suggested reading at the end of this chapter provide more details about these approaches.)

Any written agreement should document all the major points you have covered and agreed upon with the patient. Some pain-management centers use an agreement or contract with all patients as part of their standard practice, because selective use of these tools can be perceived as potentially reflecting prejudicial bias. Some programs apply these agreements or contracts with all patients who chronically receive any opioid-containing medication, and some have even proposed generalizing the practice to include a written agreement with all analgesic treatments. A clearly-written understanding of the agreed-upon treatment regimen helps to enlist patient adherence, even in regimens that do not include opioids. Although opioid prescribing may include more risk-management and monitoring obligations than non-opioid analgesic regimens, any treatment regimen carries varying degrees of benefit versus risk. Regardless of whether or not a physician is prescribing a controlled substance, there are tangible advantages to incorporating risk education information into a clear and transparent agreement process.

It is worth noting that the term “agreement” is perceived by some to be more acceptable to patients than “contract”—though from a legal standpoint, any written or oral agreement between a doctor and a patient may be considered a “contract” and both parties should treat them as such. Be sure that the terms in any agreements you use are understood by your patients, acceptable, attainable, and consistent with your practice.

Components of an Effective Agreement

Crafting these agreements may add some up-front time to patient care but provides a number of advantages that will benefit any patient and any treatment regimen. Written agreements:

- Engage the patient in a collaborative decision-making process;
- Assist in framing expected outcomes with specific functional goals and clarify the patient’s role and responsibility in attaining these goals;
- Serve as motivational reminders to the patient (and his or her caregivers) of the specific goals agreed upon with the physician;
- Serve as informed consent forms for a variety of treatment approaches. (Be sure to obtain expert advice as to what constitutes informed consent, and adequate documentation thereof, in the jurisdiction(s) in which you practice.);
- Help avoid misunderstandings or distortions of understanding over time;
- Provide a foundation for later decision-making about changes in medications if functional goals are not

achieved, or even termination of treatment if problems arise (such as aberrant behaviors that cannot be otherwise managed—see pages 61-64); and

- Potentially enhance the therapeutic relationship between patient and doctor by enabling clear communication and expectations.

Although examples of standard informed consent agreements for opioid treatment are available at professional society websites such as the American Academy of Pain Medicine (www.painmed.org), many variations of treatment agreements are possible and they can be tailored for specific types of treatment. (Some sample agreements are available through links provided at www.fsmb.org/pain.) They can offer fixed language or include “open” areas to be filled in with specific and unique aspects of the patient’s treatment plan. For example, a list of functional goals can be generated within an agreement (written in by hand or typed into a computer-based form and printed out for signing). Clinicians may want to consider adding any of the following common elements to their treatment agreements:

- Education about the risks and benefits of the agreed-upon treatment;
- Clarification of goals for treatment decisions;
- Statements relating to expectations around individualized goals and agreed-upon processes for documenting progress;
- Need for the patient to inform the treating physician of relevant information (i.e., side effects, use of other medications, changes in condition);
- Statement of time frame for which the agreement is in effect;

- Requirements for including or communicating with additional healthcare providers involved (e.g., primary care physician, pharmacist, psychologist, physical therapist, etc.);
- Who receives the agreement, where the agreement is kept, etc.;
- Statement of patient privacy rights;
- Administrative policies and expectations (e.g., missed appointment, follow-up, appearing without appointment, single pharmacy requirements, expectations of how emergencies will be handled, etc.); and
- Specific terms for administrative or other termination (e.g., abusing medication, missed appointments, violating agreement, inappropriate behavior, no improvement, pregnancy, tolerance, toxicity, etc.).

Treatments involving controlled substances may be well served by including the following additional elements:

- Patient responsibilities on improper use of controlled substances (e.g., overdosing, seeking medication elsewhere, selling medication, stopping medication abruptly);
- Limits on replacing lost medication or changing prescriptions;
- Limits on drug refills (e.g., phone allowances, mailing or faxing policy, normal office hours, etc.);
- Agreement to comply with random drug screens;
- Education on side effects (including tolerance and withdrawal);
- Education on addiction risks and behaviors;
- Pharmacy issues (e.g., one pharmacy, in-state pharmacy);

- Additional risks (e.g., interactions with other drugs, masking conditions, driving safety, misusing, pregnancy);
- Legal considerations (if applicable because of state laws);
- Need for single prescriber for all opioid prescriptions; and
- Terms regarding specific medication (e.g., type prescribed: long-acting, generic brands, etc.).

Effective Communication

In addition to including all relevant aspects of a proposed treatment in a written agreement, physicians should discuss the risks and benefits of the use of any controlled substances with the patient (or with the patient's surrogate or guardian if the patient is without medical decision-making capacity). Patients must be given the opportunity to ask questions, and physicians should "check in" with patients to ensure they understand what they are being told. A treatment that is simply handed to a patient without his or her input, or which is hastily explained with the potential to be misunderstood by a patient, will not suffice. Reviewing the consent form and not treating it as a mere formality to be buried in the chart transforms this from a perfunctory document with the sole purpose of protecting the physician's practice to a living cornerstone of understanding about the agreed upon course of care that may assist in treatment success.

Since any beneficial treatment always carries some risk, and more aggressive treatments usually carry greater risk, sharing these concerns and decisions about risk is critically important. The patients, after all, will ultimately take on the work of treatment adherence, tolerating possible side

effects and the challenges of achieving functional improvement. Moreover, they will bear the consequences of any adverse outcomes. A paternalistic approach, where the physician is the sole decision-maker, may result in half-hearted patient acceptance without investment or full commitment to the treatment. If expected outcomes are not achieved, the head of this treatment regimen—the physician—will then be responsible. Although it may be considered noble for the clinician to shoulder the responsibility, it is usually not in the best interest of the patient. The incentive for success must be with a patient who clearly understands that treatment success or failure necessitates his or her participation and investment. Although the physician has ultimate responsibility for the treatment plan, he or she may be well served to take the position of the expert advisor and consultant. The patient is best served by being put in the role of chief executive officer of his or her treatment regimen.

Effective communication and patient education are integral parts of “best practices” from both an ethical and legal standpoint. A patient who does not fully understand the potential risks and benefits of a procedure or treatment cannot be said to be truly “informed” as required by both law and the ethical guidelines for medical practice. Inadequate communication on the part of a physician and the failure to educate the patient about the treatment regimen, in other words, can have serious consequences.

Summary

Key elements of informed consent and agreements were reviewed in this chapter.

In medicine, almost any treatment plan constitutes an implied agreement between a physician and a patient. Regardless of whether or not you are prescribing a controlled substance, there are tangible advantages to incorporating risk education information into a clear and transparent written agreement. Be sure that the terms in any agreements you use are completely acceptable, attainable, and consistent with your practice. A patient who does not fully understand the potential risks and benefits of a procedure or treatment cannot be said to be truly "informed" as required by both law and the ethical guidelines of medical practice. You can create treatment agreements that help meet informed consent requirements using templates that are available online or by tailoring one from the specifics of your practice.

Suggested Readings

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Chapter 4: Periodic Review

“The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient’s state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician’s evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient’s decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient’s response to treatment. If the patient’s progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.”

—*FSMB Model Policy*

Periodic review refers to follow-up after initiating a treatment plan. The tests performed, questions asked, and evaluations made are tailored to the patient and guided by the physician’s clinical judgment. For example, a physical examination may or may not be required at each follow-up visit. (Check with your medical licensing board—some states may require a physical examination at each visit).

When controlled substances are involved, physicians must attend to predetermined treatment outcomes and be alert to a wide range of potential adverse effects. These include the common physical adverse effects of opioids such as sedation, constipation, urinary hesitancy, dry mouth, nausea/vomiting, itching, sweating, and hypogonadism, as well as more subtle behavioral effects such as mood changes, signs of drug craving or seeking, or impaired function in spheres of daily living.

Monitoring a patient's progress toward a set of functional goals (as opposed to simply asking if he or she "feels better") requires a means of measuring the progress (or lack thereof). This neither means that physicians have to become private investigators, nor that significantly more work is required as long as the goals and means of verification are clearly set up from the beginning. The key is to work with patients to create a set of realistic treatment goals and a means of charting progress towards these goals. The major responsibility of attaining those goals and presenting the evidence lies with the *patient*.

As discussed in previous chapters, patients in chronic pain suffer collateral losses that are manifested through lost function and decreased quality of life. Reviewing a patient's functional losses and desired gains is an essential part of determining an initial treatment plan and is critical to establishing useful measures for progress on return visits. Functional goals should not be extravagant or difficult to detect, but they should span as many domains of a person's life as possible: personal and social relationships, work, physical activities, hobbies, and spiritual activities. On the next page are examples of some simple functional

Functional Goal	Evidence
Begin physical therapy	Letter from physical therapist
Sleeping in bed as opposed to lounge chair	Report by family member or friend (either in-person or in writing)
Participation in pain support group	Letter from group leader
Increased activities of daily living	Report by family member or friend
Walk around the block	Pedometer recordings or written log of activity
Increased social activities	Report by family member or friend
Resumed sexual relations	Report by partner
Returned to work	Pay stubs from employer or letter confirming the patient is off of disability leave
Daily exercise	Gym attendance records or report from family member or friend

goals and ways they might be verified during periodic review.

When validation requires a report from a spouse, partner, family member, or friend, it may be useful, if the patient is willing, to have that person accompany the patient to follow-up visits. Of course, no validation scheme is 100-percent foolproof—if somebody really wants to fool a physician, he or she will find a way. But experience suggests that dysfunctional or even deceptive patients reveal themselves at some point—and repeated

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requests for the kind of evidence just mentioned forces this unmasking earlier in the course of treatment. Such patients rarely are able to keep up a charade of documenting functional improvement, particularly if their general level of function is decreasing. If patients are looking for easy access to an abusable prescription drug, they may well simply go elsewhere when they see a function-based approach or when asked for evidence of progress.

But the purpose of validating treatment goals is not simply to detect abuse of prescription drugs—though it can certainly help. The real purpose of putting “teeth” into a functional goal agreement is to motivate patients to achieve their goals and to provide the physician with the information needed to determine if a given course of treatment is working or not.

The evidence you request will vary with the patient, and your clinical judgment will dictate what evidence will be necessary, for how long, and to what degree it will be needed. Remember that the patient is largely responsible for his or her therapeutic outcomes, and part of this responsibility is to provide you with evidence of his or her progress. Meeting this part of the “deal” is a functional outcome in and of itself. If a patient is unable to document or achieve the progress outlined in an agreement, this suggests a need to reassess and possibly make adjustments.

Reviewing Functional Goals

Although functional goal-setting is critically important at the outset of a treatment plan, it isn’t a one-time event. Goal-setting is a process that evolves across the span of a long-term therapeutic treatment course. As is the case in

the treatment of so many other medical conditions, periodic review may mean that you and your patient collaboratively agree to continually move the functional goalposts. In these circumstances, the physician is akin to a sports coach. If a patient has achieved a goal or set of goals, you should recalibrate the goals to motivate the patient to reach the next level. For instance, if a patient, after three months of incremental improvement, has been able to return to swimming laps once a week, you might set a new goal of swimming three times a week. Conversely, if you've set an initial goal that is too ambitious, and the patient is becoming discouraged by the lack of progress, you can revise the goal downward or change it all together.

A common dilemma for physicians is a patient who resists engaging in physical activity toward functional goals because they report that any activity hurts too much. In such cases, rather than feeling forced to increase the dose of an opioid medication, physicians may wish to take a step back and re-evaluate the functional goals. All patients—even those with end-stage disease—can do some kind of physical motion at least some time during the day. It may appear to be so minimal that it doesn't "count" as an "activity," but it may nonetheless be a starting point for a functional goal—it all depends on how you define function. Patients with a chronic pain condition may initially need an exceedingly gentle but persistent exercise plan. This plan may need to specifically isolate and avoid using the most painful areas until some degree of physical conditioning has been established. Patients in chronic pain are not in a sprint—they are running a marathon that requires careful pacing and controlled, graduating exertion over sustained periods of time.

The patient who says that he or she can't exercise because of pain may simply be signaling that their exercise is starting at too intense a level or they are fearful of injury, increased pain, or even losing their identity as being "disabled." These myriad psychological barriers to initiating an upward cycle of improvement are beyond the therapeutic reach of prescription drugs or nerve blocks, reinforcing the importance of a team approach to integrated behavioral and rehabilitative pain management.

Almost all patients, however, can find some movement that does not cause pain. Finding that movement may not be easy, but it usually is possible. Doing that exercise for a while, and doing it repeatedly, can begin the conditioning process and allow for gradual increases in activity over time. Trying to do too much too soon will lead to failure, but this should never be an excuse for doing nothing.

Monitoring Adherence

Monitoring adherence to medication regimens is an imperfect science, but it remains an essential part of the overall process of periodic review. There are, at present, multiple ways to assess adherence but no single best approach exists. The simplest way is to just ask patients if they have been taking their medications as prescribed. Other methods include diaries, written agreements, tablet counts, and laboratory testing. Effective adherence monitoring usually involves combining several of these techniques.

Traditional methods of measuring adherence to medical therapies include tablet counts, diaries, and patient interviews. Such methods have a number of advantages as well

as drawbacks. Gross tablet counts are often unreliable because tablets may be discarded or possibly, in the case of opioids, hoarded, diverted, or sold, and offer no information about the pattern of medication use. In addition, containers can be lost or intentionally withheld. Patient diaries are questionable representations of reality, particularly when reflecting use of opioids or any other potentially abusable or psychoactive drug. They also may have the undesirable effect of keeping patients “tuned in” to their pain, rather than allowing them to “get on with their lives.” Patient interviews are subject to favorable recall bias on the part of the patient, as well as forgetfulness, especially when the interval between drug use and interview exceeds two weeks.

Laboratory testing remains a popular part of assessing adherence to a treatment regimen involving controlled substances. However, such tests can be compromised by variability and limitations in obtaining specimens, custody of specimens, laboratory methodologies, and interpreting laboratory data. Effective use of laboratory methodologies requires understanding many details of physiology, pharmacology, and toxicology, which are topics beyond the scope of this discussion. Laboratories vary in their testing thresholds and standards. Physicians must, therefore, understand these details before using the lab data with confidence.

Some labs, for example, only report values that are found to be above a certain preset threshold. Thus, a patient might have a measurable level of a drug, but since it does not exceed the given threshold, it is reported as a “negative” finding. This might lead the clinician to suspect that a prescribed drug, which should be present at the time of drug screening,

is absent because of diversion when, in fact, the drug is possibly being taken properly by the patient. A problem on the other end of the spectrum is when a patient wants to demonstrate compliance with a given medication by taking it only prior to a scheduled screen—a practice known as “white coat compliance.”

The presence and level of drugs can be detected in serum, urine, hair, and saliva. For routine drug surveillance, urine screening is most commonly used even though such screens are seldom quantitative (i.e., they usually simply confirm the presence or absence of a drug). Serum determination offers quantitative data but may not be necessary in most clinical situations. Use of serum levels of opioid analgesics in clinical practice is rarely justified, based on the wide interpatient variation in minimum effective analgesic concentration, the possible development of tolerance to analgesic or other opioid effects, and the considerable intrapatient variability in relating pharmacokinetic data to pharmacodynamic effects. Many comprehensive laboratories are expanding their urine toxicology services and limiting serum analysis to special needs.

Urine is the standard and often exclusive specimen used in laboratory screening for routine drug surveillance of opioids or other controlled substances. Advantages of urine testing include relative ease of sample acquisition, availability of rapid, inexpensive, simple testing methods, and longer duration of a positive result compared to serum. Unfortunately, urine screening is not perfect. Testing of opioids in urine is generally of two types: a screening method and a confirmatory test. Specimens found to be negative by the screening method usually

require no further analysis. It is imperative to know the sensitivity and specificity of screening tests for controlled substances, as many point-of-care screens for “ opiates” do not reliably detect any opioid other than codeine and morphine, or may not report if levels are below a certain threshold. Therefore, they may give false-negative results for semi-synthetic and synthetic opioid analgesics. Positive samples may be further studied by a confirmatory test.

Confirmatory studies are necessary when the consequences of a false-positive result are significant, or when identification of specific opioid agents is required, such as morphine and codeine, rather than a class-specific opiate-positive finding. In such cases, it is advisable to use a laboratory that complies with the Substance Abuse and Mental Health Services Administration (SAMHSA) standards and to use accepted chain of custody procedures for obtaining and handling specimens. (The SAMHSA standards are available at: www.workplace.samhsa.gov/)

Managing Non-Adherent Patients

Suspicion that a patient is non-adherent should prompt a thorough investigation of underlying causes, *not* a summary rush to judgment. We all must acknowledge that in managing challenging cases and difficult patient-physician relationships, the problem is not always just with the patient. The way we interact with these patients will impact the relationship and influence treatment outcome. The difficult patient may raise a host of reactions in the clinician and recognizing these reactions is critically important to delivering the best possible care.

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Be aware of the distinction between *pseudoaddiction* and addiction. Patients who are receiving an inadequate dose of opioid medication often “seek” more pain medications to obtain pain relief. This is called pseudoaddiction because healthcare practitioners can mistake it for the drug-seeking behavior of addiction. (Recall that addiction is when a person loses control over the use of a substance, uses it compulsively, and continues to use it despite harm and dysfunction.) Some common signs of pseudoaddiction resulting from inadequate analgesia are:

- Requesting analgesics by name,
- Demanding or manipulative behavior,
- Clock watching,
- Taking opioid drugs for an extended period,
- Obtaining opioid drugs from more than one physician, and
- Hoarding opioids.

Note that these same behavioral signs can indicate addiction. One way to discriminate between the two is to observe as closely as possible the functional consequences of opioid use. Whereas pseudoaddiction resolves when the patient obtains adequate analgesia, addictive behavior does not. Consultation with an addiction medicine specialist or psychiatrist may be necessary at the point when addiction becomes a concern. As always, high vigilance and tempered judgment are required with certain signs that may or may not indicate an abuse problem. (See the chart on the next page.)

It may be tempting to assume that patients with chronic pain and a history of recreational drug use who are not adherent to a treatment regimen are abusing medications. But other causes of non-adherence, such as those discussed above, should be considered before a judgment is

(Behaviors LESS indicative of addiction)	(Behaviors MORE indicative of addiction)
Express anxiety or desperation over recurrent symptoms	Bought pain medications from a street dealer
Hoard medications	Stole money to obtain drugs
Taken someone else's pain medications	Tried to get opioids from more than one source
Aggressively complained to doctor for more drugs	Performed sex for drugs
Requested a specific drug or medication	Seen two doctors at once without them knowing
Used more opioids than recommended	Performed sex for money to buy drugs
Drink more alcohol when in pain	Stole drugs from others
Express worry over changing to a new drug even if it offers potentially fewer side effects	Prostituted others for money to obtain drugs
Expressed concern to physician or family members that pain might lead to use of street drugs	Prostituted others for drugs
Asked for second opinion about pain medications	Prescription forgery
Smoke cigarettes to relieve pain	Sold prescription drugs
Ever used opioids to treat other symptoms	

Source: Passik, S.D., K.L. Kirsh, K.B. Donaghy, and R. Portenoy. Pain and Aberrant Drug-Related Behaviors in Medically Ill Patients With and Without Histories of Substance Abuse. *Clinical J. Pain*, 2006, 22(issue):173-181. (see p. 65, no. 1)

made. If for any reason a physician's suspicions are aroused, he or she has a duty and obligation to increase his or her vigilance through closer observation, increased testing, and greater involvement of consultants or other supportive clinicians. This approach is no different than for the management of any patient in whom you suspect toxicity from a drug therapy. Use of the type of patient-physician agreement detailed previously can guide such a process and may make implementation less confrontational or controversial.

Components of Effective Follow-Up

Progress toward treatment goals is seldom smooth. Reversals and patient frustration are common. Your goal is to help patients see the long view, support their efforts, and troubleshoot problems. Here are some tips for effective periodic review:

- Careful and compassionate listening;
- Attention to the entire patients, not just to their pain;
- Referral to related health professionals as needed to support a treatment plan (e.g., other medical specialists, mental health professionals, physical therapists, social workers, support group, etc.);
- Adjustments to pain medications if indicated and reasonable in the larger context of the patient's situation—linking continuation of these medications to evidence of reasonably improved function or stabilization at an acceptable level;
- Modifications, if needed, of functional goals. Goals can be scaled back if progress is lacking, or can be made more aggressive if progress is rapid;

- Revising the patient-physician agreement as needed to reflect changes in treatment regimen, functional goals, or other aspects of the patient's condition; and
- Complete documentation that offers transparent descriptions of the risks involved in the ongoing treatment plan, the risks of not taking such actions, and the ongoing risk management strategy.

Summary

This chapter examined the need for periodic review of treatment outcomes for patients in pain, particularly when controlled substances are involved. Physicians must closely attend to expected treatment outcomes and be alert to a wide range of potential adverse effects. Monitoring a patient's progress toward a set of functional goals requires a means of measuring the progress (or lack thereof). But the responsibility of attaining those goals and presenting the "hard data" may be best held with the patient. The purpose of validating treatment goals is not simply to detect abuse of prescription drugs, it is to motivate patients and help you determine if treatment is working or is problematic for any variety of reasons. Sometimes functional goal-posts must be moved in order to maintain a patient's motivation. In the course of periodic review, suspicion that a patient is non-adherent should prompt a thorough investigation of underlying causes, not a summary rush to judgment. It is easy to mistake pseudoaddiction for the real thing. One way to discriminate between pseudoaddiction and addiction is that pseudoaddiction resolves when the patient obtains adequate analgesia; addictive behavior does not.

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Chapter 5: Referral and Patient Management

“The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.”

—FSMB Model Policy

Patients in chronic pain can present an extremely complicated picture. As we've seen, the subjective nature of pain is difficult in and of itself, but the collateral impact of patients' pain may disrupt their work and personal lives. In addition, patients in pain may have comorbid physical or emotional conditions for which they may be taking multiple medications. This complexity can challenge even the most broadly trained physicians, and can lead them into diagnostic and treatment areas that lie outside their expertise and professional comfort.

The tradition of medical referral exists to address this reality. In caring for patients in pain, referral to specialists or sub-specialists is common—and, indeed, often

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necessary—for the typical clinician. Very few of us can practice effectively without help on a regular basis from colleagues who offer more specialized skills, perspectives, and capabilities in certain areas than we possess. Recognizing our own clinical limitations is a vitally important facet of medical professionalism. Because chronic pain affects every sphere of a patient's life, physicians should expect that they will need to request help from colleagues with expertise in diverse disciplines, such as mental health, addiction, physical rehabilitation, or any other medical or surgical subspecialty.

Here are a few basic requirements for facilitating the referral process:

1. Don't delay.

Almost all medical conditions or problems are easier to tackle early in their development rather than later. This applies with particular gravity to the case of chronic pain treatment with controlled substances. Valuable time can be wasted if a physician stubbornly tries to solve all problems by him or her self.

2. Invest in the pre-referral process.

Try to obtain the basic information that a consultant will need to efficiently evaluate your patient. This may seem obvious, but sometimes obtaining the required medical records, prescription records, or lab results can be logically complicated.

3. Be as specific as possible in your request.

The more vague the referral, the less useful the consultation. Tell your consultant exactly how he or she can help you and your patient, and then be transparent in your documentation about the reason for consultation

and how it may affect treatment decisions and patient management. In particular, always state directly what you hope to achieve by your referral.

4. Know your consultants.

Survey your most knowledgeable colleagues to develop (and keep updated) a list of potential consultants. Think “out of the box” about consultants (i.e., those outside your institution, at a university, or in private practice). Cultivate professional relationships with such consultants to facilitate input by phone, email, or in-person meetings.

5. Plan in advance.

When treating patients with opioids it is ideal to have both a “go-to” pain specialist and an addiction specialist available if consultation becomes necessary. Unfortunately, these two types of specialists are often in short supply, and many physicians struggle to find specialists to accept their referrals. An optimal level of care, when possible, would include consultants who can assist you with your patients and continue to give you guidance after most of the patients have been returned to you for chronic treatment. If it evolves that a patient is to receive ongoing care from a consultant, this understanding should be worked out between you and the consultant, so that the patient receives clear messages and clear treatment.

6. Expect your consultant to communicate with you.

This may seem fundamental to any consultation, but problems can arise when the consultant treats your patient without communicating the treatment plan with you or fails to keep you informed as treatment progresses. This is a two-way street, of course. You must be

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available to discuss the plan and progress with the consultant, as well. Often this can be done with an exchange of notes, but more immediate contact by phone and email may be most expedient and preferable.

Referral for Patient Behavior Issues

One of the more common reasons a physician may need to seek help by referral is with patients who are difficult because of their behaviors. Primary care clinicians or specialists must both maintain an alliance with their patients and set boundaries within which good healthcare can proceed and harm can be avoided. When the relationship becomes strained by constant demands or other difficulties, it can be helpful to bring in a second party, such as a pain consultant, who can offer an objective perspective and who has not yet been influenced by the patient's mixed messages or inconsistent behavior. (Effective pain management consultants should offer strategies that preserve the self-esteem of both the patient and any staff involved. They should assiduously avoid pointing blame or embarrassing the patient, physician, or staff.)

Patients dealing with chronic pain can exhibit a range of behaviors that can challenge the most poised and professional clinician. Patients in pain may have many reasons to be angry, argumentative, mistrustful, anxious, and depressed. (Depression and anxiety disorders are two-to-three times more prevalent among patients in chronic pain than in the general population.) These patients may strongly disagree with the physician's assessment or treatment and can have idiosyncratic reactions to procedures, such as a severe provocation of pain in the absence of any procedural

complication. Even the most mild-mannered and polite person can become demanding and even obnoxious under the lash of constant pain, sleep deprivation, hassles associated with working through the maze of healthcare bureaucracy, and frustration with physical limitations that make even the simplest activities, such as tying one's shoes, a struggle. They can also display destructive behaviors, such as threats of suicide, self-mutilation, extreme noncompliance with treatment, and opioid misuse.

Aberrant patient behaviors do not exist in a vacuum, of course. Sometimes the physician can weaken the relationship as well. In the pressure-cooker of daily practice, it is all too easy to lose patience, compassion, warmth, and one's sense of humor. As a result, physicians can be perceived as arrogant, uncaring, unintelligible, or rushed. In any situation involving a patient's aberrant behavior, the source of the difficulty lies either with the patient, the physician, or (most often) in a combination of personality attributes embedded in a complex set of stressful circumstances.

Managing Difficult Patient-Physician Relationships

Although referral for difficult patient behaviors is legitimate and often desirable, it is also true that physicians can work to improve their own practices and learn ways to deal early with potentially difficult situations. Ideally, we try to act well before the patient-physician relationship has degenerated to the point where referral is a means to avoid the patient. Indeed, although aberrant patient behavior is certainly challenging, successfully dealing with such behaviors can be rewarding. Most difficult behaviors will be found, upon compassionate reflection, to be rooted in

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patient fear, frustration, bias, anxiety, past trauma, or simply the corrosive effects of pain, fatigue, and stress. In many ways, the patients displaying the most severe behaviors are the ones most in need of a physician's help. Disliking a patient is never comfortable, but it's important that you not deny or avoid recognizing those feelings. Self-awareness can allow you to effectively isolate the potentially harmful reactions that accompany such personal dislike. Moreover, awareness can be the tool that allows you to retain the elements of care that make your practice viable and worthwhile.

Aberrant patient behaviors, such as manipulation, verbal abuse, or hostility, may promote clinical mistakes that would never be made in typical non-threatening interactions. The most classic mistake is for a physician faced with a difficult patient to rush an examination or treatment decision in a desire to get to the next case or to prompt the patient to move on to somebody else who will take responsibility for his or her care. This is like driving in a rain storm with slippery roads and, instead of slowing down, you speed up—thinking that the faster you go, the sooner you'll be out of the storm. This is obviously a formula for disaster, either in a car or in the clinic with a challenging patient.

The only universal rule in difficult situations is to SLOW DOWN! Listen and watch more purposefully than usual. Take your own pulse—ask yourself what you are feeling and why. Check your assumptions about the case and ask whether you are being pressured to do something without justification. Perhaps you need to add a follow-up visit or a consultation with another physician before jump-

ing into therapeutic action. A common-sense solution is usually available if you take the time to find it.

Here are some practical rules of thumb for dealing with aberrant patient behaviors:

- 1. Listen reflectively.** Listen to the patient in order to determine his or her understanding of the problem, disease, or expectations from treatment, including any religious or cultural factors that might be influencing his or her beliefs. Ask questions that confirm or correct your understanding or assumptions about the case.
- 2. Assume a non-confrontational stance.** Dealing with a difficult patient can easily spiral into a battle of wills or wits that will solve nothing. Try to approach patients with the assumption that you are both on the same side. If a patient says or does things you disagree with or feel are groundless, pause and then reflect back what he or she just said rather than automatically rejecting, denying, dismissing, or contradicting. This takes practice and patience. If sometimes you “lose it” and find yourself stuck in a thicket of heated emotions, step back (literally, if necessary) and collect yourself. (Don’t worry, this happens to everyone sooner or later.)
- 3. Avoid paternalistic interactions.** Remember that patients are in charge of their own health decisions. Rather than assuming the role as key decision-maker or all-knowing sage, physicians can help themselves and their patients by framing their role as a partner or “medical consultant.” This means that the patient can choose to accept or reject physician recommendations, stay with a physician, or see someone else. This shifts responsibility and the direction of information flow from the perceived

“omnipotent” physician dictator, who is telling the patient what to do, to the “strong advisor” physician who offers realistic solutions for the client to adopt.

- 4. Include the patient in planning the treatment regimen.** The largest single determinant of the success of a treatment regimen may be a patient’s ability and willingness to carry it out. Patients who participate in creating their treatment plan and who understand its underlying rationale may be much more likely to adhere to it than those who are merely told what to do.
- 5. Focus on the big picture.** Patients understandably focus narrowly on their pain, illness, or incapacitation and their words or actions arise from that tunnel vision. Physicians can “pull back” to see not only the present situation, but the larger life context of the patient, antecedents that might be contributing to the problem, and the path from the present pain to a future function-based goal or outcome.
- 6. Set limits for acceptable behavior.** No patients, regardless of the pain they may be in, have the right to insult, verbally abuse, threaten, or physically harm a healthcare worker. At the first instance of such behavior, you can set or reinforce clear limits. In such cases, firmly and clearly establish (1) that the behavior is unacceptable, and if repeated, you will remove yourself from their care until acceptable behavior is possible; and (2) that you will have to evaluate whether ongoing care within your practice is possible. You could also turn care over to another physician in such instances, since sometimes a different personality type may work better with certain patients. But such a transfer must always be based on the patient’s best interest,

with adequate transfer of records and information to assist in optimal care in the future.

7. Maintain safety. Keep firmly in mind that immediate safety is the first priority, and if patients threaten to harm themselves or others (including you), they may need to be physically restrained and assisted by either the police or psychiatric professionals. Maintain procedures within your office that promote easy exit from a room in which you might feel physically unsafe or develop strategies through which help can be immediately called for and received. Safety for patients, your staff, and yourself must be your highest priority. Determine in advance what rules and policies govern your institution or practice setting, and strictly adhere to any institutional policies or state laws in such cases. Educate all staff on policies and procedures, and practice your response to potential scenarios before they occur.

A specific type of difficult patient behavior that is more likely to crop up in the context of prescribing controlled substances is deception and distrust. Some patients lie, but only sometimes does a lie represent a real threat to the therapeutic relationship and the effectiveness of a treatment regimen. If you suspect a patient is lying and you feel the issue is important, you may want to deal with the issue directly. In doing this, it is again helpful to frame your role as that of a professional consultant, with the patient in charge of ultimate decision-making. Your role is not to judge or punish but to present facts and find solutions.

It can be difficult, but it is helpful to try to see lies as revealing important information about the patient. Many of us react to being lied to with offense and hurt feelings.

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However, every clinician will probably be lied to from time to time. It's a "yellow light" signaling caution, and in and of itself, does not require rejection or termination. Your task is to try to find the truth without stigmatizing or harming the patient and without making yourself feel better at the expense of the patient.

Treatment Termination

Aberrant patient behaviors will occasionally require that the patient be dismissed from a practice. Physicians can, and should, have a "zero tolerance" policy for illegal behaviors (e.g., selling prescription medications, threatening violence, or forging physician signatures) or dangerous situations. Other circumstances can make "administrative termination" necessary, such as an opioid-addicted patient who refuses treatment for his or her addiction.

In such cases, abandonment must be avoided and the patient should be informed of the reasons he or she can no longer be treated by you. Such messages may occur during a face-to-face visit and followed up with a formal letter, and it may be advisable to include a witness, such as a nurse or medical assistant. In the absence of such a meeting, since face-to-face opportunities may simply be impossible, a certified letter can be used. You can specify the terms of separation (e.g., 30 days after receiving the letter, the patient will no longer be admitted to your practice). Exactly how to achieve the best result for the patient and yourself, however, will require individualization and possibly, consultation with a bioethics committee, a risk-management specialist, or an attorney.

All physicians are bound ethically not to abandon a patient in their care. Exactly how you fulfill this responsi-

bility may also require professional consultation. In some states, there may be legal or regulatory requirements for termination of a patient-physician relationship. In many situations, you may give the patient names of other providers in his or her community or contact information for the local medical society, from which the patient can obtain a list of providers. Last, at discharge, you must consider how the patient will tolerate treatment discontinuation without harm, and, in cases involving such drugs as opioids, benzodiazepines, anticonvulsants, and antidepressants, and others, safe discontinuation may require a tapering schedule.

Summary

This chapter has discussed the common need to seek consultation from allied health professionals when dealing with patients in chronic pain. It has explored the related issue of managing the patient whose behavior has become difficult. We have seen that, although aberrant patient behavior can be difficult, it also can be potentially rewarding. Challenging behaviors usually arise from fear, frustration, poor pain control, or the corrosive effects of fatigue and stress. As such, the patients behaving “worst” are often the ones most in need of a physician’s help. Working to expand self-awareness and cultivating a network of other professionals whom you can call for help can enable you to remain in control and retain the elements of care that make your practice effective for your patients and gratifying for you—even when confronted by the most difficult patients.

Chapter 6: Documentation

“The physician should keep accurate and complete records to include: the medical history and physical examination; diagnostic, therapeutic and laboratory results; evaluations and consultations; treatment objectives; discussion of risks and benefits; informed consent; treatments; medications (including date, type, dosage and quantity prescribed); instructions and agreements; and periodic reviews. Records should remain current and be maintained in an accessible manner and readily available for review.”

—FSMB Model Policy

Documentation is important in the management of any patient, and particularly so when opioids or other controlled substances are used as part of pain management. Not only is clear, consistent, and detailed documentation part of “best practices,” it also is a necessity for reliable and legitimate assessment of the effectiveness of a longitudinal treatment regimen. Although documentation is valuable as a record of one’s rationale for a particular treatment regimen and offers obvious benefits and protection for the treating clinician, the focus here is on creating and maintaining a solid record because it is in the patient’s best interest.

Given the impossibility of remembering the details of all your patients, a written record may be the only way to keep track and to spot trends over time, whether they be

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progress toward functional goals, severity of side effects, or subtle changes in patient demeanor or affect. In the event of a need to refer a patient to a specialist, careful documentation will enable optimal continuity of care.

Everybody wins when clinical behavior and decision making are as transparent as possible.

Transparent documentation is the part of the process where a physician records as clearly as possible how the risk/benefit analysis was applied and how it played out for a particular patient. This means that, not only has the basic care plan been documented, but the decision-making process and the rationale behind specific courses of treatment also have been adequately considered. Remember that both treating and not treating involve risks. Physicians cannot avoid managing risks. Considering the risks and the contrasting benefits of any treatment is a cornerstone of clinical practice, but many of us do not emphasize this in our clinical notes. Everybody benefits when clinical behavior and decision making are as transparent as possible.

This means that not only has the basic care plan been documented, the decision-making process and the rationale behind specific courses of treatment also have been adequately communicated. Remaining focused on the risks being considered and the contrasting benefits of any treatment is a cornerstone of clinical practice, but many of us do not emphasize this in our clinical notes. Remember that both treating and not treating involve risks—physicians cannot avoid being risk managers. Transparent documentation is the part of risk management where a physician records as clearly as possible how the risk/benefit analysis was applied and how it played out for a particular patient.

Many computerized systems are now available for the acquisition, storage, integration, and presentation of medical information. Most offer advantages that will benefit both patients and physicians, because, among many other advantages, records are kept up to date and information relevant to prescribing or treatment is instantly available. In the future, even more sophisticated information systems may become available that include customized and automated patient-education and patient-assessment tools. Such systems offer the promise of greatly improving practice efficiency and patient satisfaction.

Clear documentation, however, is not dependent on computerization or electronic record-keeping; it's dependent on a commitment to achieving clear and enduring communication in a systematic fashion. Paper and pen or the dictated word still can be sufficient.

Elements of Effective Documentation

As a broad guide, six basic elements of a patient's care should be documented in writing: (1) Assessment, (2) Treatment Agreements, (3) Education, (4) Action Plans, (5) Outcomes, and (6) Monitoring.

Each clinician has to use clinical judgment to determine how often each element of documentation is required to be repeated. Each of these should at least be part of initial evaluations and considered for updating on periodic review of the case. Regardless of the system used to document clinical decisions, detailed, readily available, and transparent documentation in the patient medical record must cover a broad range of areas, including the following: (However, assessing all areas is not required at every visit and depends on patient and treatment variables.)

- Medical history and physical examination;
- Diagnostic, therapeutic, and laboratory results;
- Evaluations and consultations;
- Records of periodic reviews of patient behaviors, side effects, and functional outcomes.
- Medications (including date, type, dosage, strength, and quantity prescribed);
- Pain intensity levels;
- Levels of functioning, and quality of life;
- Subjective complaints of the patient;
- Objective findings by the physician;
- Diagnostic impressions, and potential treatment options;
- Treatment objectives
- Other specific aspects of the treatment or treatment program;
- Discussion of risks and benefits;
- Informed consent;
- Instructions and agreements; and
- Plans for periodic review of patient behaviors, side effects, and functional outcomes.

Specifics of Documenting Controlled Substance Prescriptions

Each state has laws that govern the appropriate prescribing of controlled substances and prescribers are required to know and abide by these regulations. Each state's board of medicine (titled differently by each state) oversees the professional conduct of physicians, or more precisely, the conduct of physicians who are practicing within the bounds of medicine. As such, a medical board review of a physician's practice will focus on whether or not care is delivered within or outside the

standards of care. Demonstrating whether a practice is within the standard of care usually relies to a large degree on a physician's self-generated documentation of his or her work. It will be through this documentation that reviewers assess the level of awareness of risks involved in the delivery of care and the rationale for the choices that were made. In medical practice, there are often no absolutes on the exact treatment for every patient, and physician judgment is often the mitigating variable. Therefore, understanding the elements of the physician's judgment, which is best supported through transparent documentation, may be all that a medical board investigation has to go on to judge a physician's practice. Moreover, most medical boards will consider maintenance of adequate records of patient care as a requirement in and of itself.

Federal law also governs the appropriate prescribing of controlled substances and prescribers are also required to know and abide by these regulations. The authority to prescribe Schedule II-V drugs is granted by the Federal Government through the Drug Enforcement Administration (DEA.) The DEA, which resides within the Federal Department of Justice, describes a number of specific steps that practitioners must follow to document the use of controlled substances. These procedures may, or may not, correspond with state-specific standards. Each practitioner, therefore, must fully understand his or her state rules as well as follow the DEA requirements.

A revised DEA practitioner's manual was introduced in September 2006 and is available online at www.deadiversion.usdoj.gov. It summarizes and explains the basic requirements for prescribing, administering, and dispensing controlled substances under the Controlled Substances Act (CSA) and

the Code of Federal Regulations. Although all prescribers of controlled substances must know these federal requirements, a complete review is beyond the scope of this book. The Appendix includes links to relevant DEA websites, including the 2006 DEA Practitioner's Manual. Excerpts from that manual that relate to general aspects of prescribing controlled substances, including requirements for appropriate documentation, are posted on FSMB's website: www.fsmb.org/pain.

Accurate Coding

Nowhere are information systems more detailed and often idiosyncratic than in the area of communicating with payers for authorization and billing. Although learning the details of these requirements can be formidable, physicians who fail to adequately conform to a documentation system can compromise both the overall efficiency of the system and the care their patients receive. Documentation requirements and procedures may vary considerably across institutions, and across administrative or reimbursement systems within a single institution or practice.

Documentation for coding purposes is often compromised by providing inadequate specific information to accompany a code or assuming that the person reading the document (often a non-medically trained "coder") understands the implications of examination results or other details of the history or treatment plan. It has become an all-too-apparent reality that coders are limited in what they can code, and physicians must understand basic documentation requirements for coding. Coders are not allowed to "interpret" and must depend on the quality of the documentation in the medical record. For instance, if a physi-

cian writes that the patient has a hemoglobin of 5.0 in the medical record, the coder cannot interpret this as anemia, even if he or she knows enough to suspect this finding. In order to code it, the physician must specifically document anemia in the record—in this case example, there might also be a need for additional information such as other specifics around the type of anemia and its relationship to other comorbid diagnoses that may impact the accuracy of coding assignment. In general, physicians should document their suspicions to the highest degree known, yet another example of the benefits of transparency.

Proportionate Prescribing

At times, prescribers may feel inclined to assist their patients by prescribing more doses of a scheduled drug than the patient may need to manage an acute pain condition. This is particularly the case for schedule III medications such as hydrocodone or schedule II drugs such as oxycodone.

For example, a patient with an acute backache might be anticipated to need hydrocodone with acetaminophen several times over several days. In some cases, this might amount to a maximum of eight tablets per day over two to three days, perhaps for a maximum of five days. Pain lasting beyond this period might suggest that the patient should be re-evaluated. Although the total anticipated need would add up to a maximum of 40 tablets, physicians too commonly write a prescription for 90 to 150 tablets, perhaps with a few refills, innocently believing it is in the patient's interest to have more on hand if pain persists.

However, in the current environment where prescription opioids are increasingly diverted or abused—sometimes

from households where medicine cabinets with leftover medication are accessible to children, teenagers, and others—vigilance is required more than ever. This includes tailoring the amount of a scheduled drug to a reasonable assessment of how much you think your patient will need.

Some physicians may consider a schedule III drug such as hydrocodone to be relatively safe, unaware that hydrocodone is the most prescribed medication in the United States¹ and is widely sought after and diverted for nonmedical purposes. Regulators recognize that medical judgment is not a science but is nonetheless required for optimal clinical efficacy and overall safety—and this includes prescribing appropriate amounts and refills that are proportionate to expected clinical outcomes.

Summary

Although it comes near the end of the list of guidelines in the FSMB *Model Policy*, documentation is an essential component at every step of the process of delivering appropriate pain care. Effective documentation is vital to supporting all of the other elements of the FSMB *Model Policy*. Moreover, complete documentation is essential to indicate compliance with state and federal laws that govern prescribing controlled substances. Last, documentation is required for supporting coding, billing, and reimbursements.

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Chapter 7: Compliance With Relevant Law

“To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.”

—FSMB Model Policy

As useful as they may be, opioid medications are scheduled as controlled substances because they also have a potential for abuse. Consequently, they and the healthcare professionals who prescribe, administer, or dispense them are regulated by a complex series of federal and state policies on controlled substances, as well as other state laws and regulations that govern healthcare practice. Such policies are intended to prevent drug abuse and substandard prescribing practice. But in some cases, they can have impact that goes beyond their intended purpose in ways that can hamper legitimate medical practices and create barriers for caregivers and patients.¹

Although considerable progress has been made in the past decade to amend state laws in hopes of striking balanced regulatory policies, significant state-to-state inconsistencies remain. Some state policies may create particular

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practice standards that differ from national conventions. Growing attention to the separate public health crises of undertreated pain and prescription drug abuse are leading to calls for more circumspect and specific regulations. Some state laws have been recently revised or are in the process of revision. In some states, however, there still may be legal language in the professional and business codes that could raise concerns by:

- Limiting the amounts of opioids that can be prescribed and dispensed;
- Requiring special government-issued prescription forms;
- Restricting access to patients in pain who have a history of substance abuse or addictive disease;
- Using antiquated and ambiguous language that can confuse patients in pain with people who have addictive disease; or
- Requiring opioids to be only a treatment of last resort.

Language that can enhance pain management is now frequently being added to state policies and laws. However, there remain some states in which the need for appropriate pain care is not well articulated. For example, some states do not recognize that controlled substances are necessary in some cases, or that pain management is an integral part of the practice of medicine.

It is imperative that physicians are thoroughly familiar with their own state's laws and regulatory practice standards. (Access to these laws, or summaries of the laws, is available through the Federation of State Medical Boards website: www.fsmb.org/pain.) Unfortunately, evidence suggests that many physicians remain ignorant of the state reg-

ulations under which they practice. This may have divergent consequences: On the one hand, some physicians may limit their use of controlled substances in the mistaken belief that their state laws are restrictive or overly punitive; on the other hand, some physicians may be practicing in a manner inconsistent with accepted standards and this might be viewed as potentially suspicious by their state's regulatory agencies that oversee medical practice.

Physicians also must have a firm grasp of the federal laws relating to controlled substances. These laws are articulated in the federal Controlled Substances Act (CSA), which attempts to balance the competing demands of both control and availability. Under this act, licensed professionals can prescribe, dispense, and administer controlled substances for legitimate medical purposes in the course of professional practice. (Note that most opioid analgesics are Schedule II drugs although a few, which happen to be the most prescribed, are schedule III drugs—Schedule I drugs such as heroin and LSD are considered to have no legitimate medical uses.) The “control” portion of the CSA attempts to prevent diversion, establishes a system of secure manufacture and distribution, requires record-keeping procedures, and sets up penalties (including criminal prosecution) for violating its provisions.

Prescription Monitoring Programs

In response to the problems of drug diversion and abuse of prescription medications, the Federal Government and many states have promoted prescription monitoring programs (PMPs). Typically, PMPs collect prescribing and dispensing data from pharmacies, conduct reviews and analyses of the

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data, and disseminate the data to appropriate regulatory and law enforcement agencies. Some have begun to make these data available to clinicians and a few have even made the data readily available at the point of care. It seems certain that more states will be moving in this direction in the future.

Following the lead of New York State in the 1910s, California and Hawaii enacted PMPs in the 1940s. By the 1980s, seven more states had added PMPs. These early programs required that physicians use state-issued multiple copy forms (duplicate or triplicate) to write prescriptions for Schedule II controlled substances, and that pharmacies return one copy to the state after dispensing a drug. Physicians were usually required to obtain prescription forms from a state law enforcement agency and some states charged a fee for the forms or limited the amount that could be ordered at any time.

Only one multiple copy prescription program still exists because of the barriers to care that most caused, as well as the advent of technological solutions that use computerized information systems to take the burden of prescription monitoring away from the front lines of clinical care. Most states are now moving to computerized PMPs. In such systems, pharmacies transmit data to the state on controlled substances prescriptions. Although there is currently a federal program that supports individual states in their efforts to implement a PMP (National All Schedules Prescription Electronic Reporting Act of 2005), in practice, PMPs take different forms because each state government is charged with determining the goals, structure, and organization of its

program. Variation between states is still common, even in states that border each other and must deal with patients crossing state lines for care.

Certain characteristics of PMPs can have a deterrent effect on potential criminal activities. For example, some state authorities report that use of tamper-resistant prescription forms significantly reduces or eliminates prescription forgery. Thus, while government-issued serialized prescriptions have largely been abandoned as useful tools for prescription monitoring, the use of security paper that is tamper-resistant is increasing. These security-paper prescription forms employ the same technology that has long been used on personal bank checks or on paper money—these include a watermark that may be viewed at a certain angle, photochromic features that produce an image such as the word “void” if the paper is copied or scanned by a light source, or even thermochromic features in which the paper changes color when touched by warm fingers or a heat source. In addition, PMPs that make prescribing information available to clinicians at the point of clinical care may be useful for identifying “doctor shopping.” An individual who is identified as doctor shopping should have his or her treatment plan re-evaluated, may need additional guidance and education, may be directed into treatment for chemical dependency, or may be prosecuted, depending on the circumstances of the case.

To date, not all PMPs have been created equal, however, and some may have inadvertently erected barriers, either overt or implicit, to the appropriate prescribing of opioids for legitimate medical purposes.⁴ Some programs may have sent unintended and subtle messages to physicians that

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encourage them to be stingy with or paranoid about prescribing strong pain medicines. Data show that physicians recognize such messages and alter their practices accordingly, often with detrimental results. For instance, California had the oldest PMP system in the United States, which used serialized triplicate prescriptions solely for Schedule II drugs. On several occasions, pain-care advocates tried to convince the California legislature to rescind the triplicate program as it was widely believed to be a barrier to adequate pain management. On each occasion, arguments were made that if California removed its triplicate-based PMP, it would see markedly increased Schedule II prescribing, which often provides optimal treatment for patients with severe chronic pain, but also increases abuse of these medications. The assumption was that maintaining low levels of Schedule II drug prescribing was protecting citizens from drug abuse. The triplicate PMP was ultimately removed when the legislature was able to see that while the triplicate PMP clearly resulted in low Schedule II prescribing, including low prescribing rates of sustained release oxycodone, California had a disproportionately high rate of Schedule III opioid prescribing and abuse, particularly hydrocodone (found in products compounded with acetaminophen such as Vicodin, Norco, Lortab, etc.) Ironically, hydrocodone is the most prescribed drug in the United States, prescribed in far greater numbers than any other opioid.

The California experience was predictable. It is well-established that when physicians are faced with barriers to prescribing a certain type of medication, they will often prescribe around that barrier, turning instead to drugs that are perceived to be less scrutinized, even if they are less effica-

cious and/or potentially harmful. This pattern is known as the substitution effect.⁵ The problem of the substitution effect is one example of how we may view a set of data relating to the drug abuse problem and draw conclusions that neither factors in all of the relevant variables nor anticipates the full collateral impact on the drug-abusing population or on patients with a legitimate need for controlled substances.

Contemporary PMPs are not intended to interfere with medical practice, and attempts are increasingly being designed to reduce potential barriers to care. Unlike PMP programs of the past that were intrusive at the point of clinical care, newer electronic-based PMPs collect data behind the scenes of clinical care. Likewise, contemporary PMPs typically do not require physicians to obtain prior approval to issue prescriptions and they do not impose limits on the quantity that may be prescribed. Limitations on prescribing controlled substances do exist, but are governed by laws that are separate from those related to PMPs. For instance, federal law prohibits prescribing refills on Schedule II drugs, and recently the DEA has made adjustments to exactly what constitutes a refill. Likewise, some state laws may limit quantities that can be prescribed in one prescription, but such limitations are completely distinct from the individual state's PMP.

More states are likely to institute PMPs in the future because of the 2005 congressional approval of the National All Schedules Prescription Electronic Reporting Act (NASPER). This law instituted a program that offers individual states funding for establishing PMPs. Although NASPER was hailed as a major tool for clinicians, it did not mandate that the collected information would be directly available to physicians at the time that they treat

their patients. However, PMP data should and likely will be more available to clinicians at the point of care. Using these data may prove to be increasingly important in the management of patients who use controlled substances.

Federal Guidelines for Prescribing Controlled Substances

As noted in Chapter 6, the DEA released an updated Practitioner's Manual in September 2006. It summarizes and explains the basic requirements for prescribing, administering, and dispensing controlled substances under the CSA. The complete manual is available online (www.deadiversion.usdoj.gov) and physicians are urged to read it carefully. This internet website is also of value for any updates that may occur. Moreover, the DEA also issued a clarification of its policies relating to the use of controlled substances for pain that appeared in the September 6, 2006 Federal Register (Vol. 71, No. #52716- 52723, 172, 21 CFR Part 1306.) This document is titled Dispensing Controlled Substances for the Treatment of Pain. Select passages that are posted on www.fsmb.org/pain offer DEA clarification on the following topics:

- Purposes and Structure of This Document
- The Statutory Role of DEA in Regulating the Prescribing of Controlled Substances
- The Meaning of the "Legitimate Medical Purpose" Requirement
- Other Recurring Questions
 - What are the potential signs to a physician that a patient might be seeking drugs for the purpose of abuse or diversion?

- What are the general legal responsibilities of a physician to prevent diversion and abuse when prescribing controlled substances?
- What additional precaution should be taken when a patient has a history of drug abuse?

The DEA also issued a statement that proposed amending its regulations to allow practitioners to provide individual patients with multiple prescriptions, to be filled sequentially, for the same Schedule II controlled substance, with such multiple prescriptions having the combined effect of allowing a patient to receive over time up to a 90-day supply of that controlled substance. As in the case of the documents discussed above, this notice was also issued in the September 6, 2006 Federal Register (Vol. 71, No. 172, # 52724-52726, 21 CFR Part 1306.) It is titled: Issuance of Multiple Prescriptions for Schedule II Controlled Substances; Proposed Rule. In this Notice of Proposed Rule Making, DEA requested public commentary and received a number of letters from interested professionals, societies, and consumers. A Final Rule is said by DEA to be forthcoming.

Summary

Current federal regulations, emerging state laws, and in particular, the FSMB *Model Policy* seek a rational balance that supports society's need to be protected from drug abuse and to receive effective treatment for pain. Physicians who find such balance in their practice will likely find themselves congruent with the goals of regulators and, most important, with the needs of their patients. New or revised regulations, and

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the reality of changing or inconsistent existing regulations at both federal and state levels, reinforce the fundamental message of this chapter and the FSMB *Model Policy*: physicians must take the time to educate themselves about the realities of the legal environment in which they practice and remain up to date on any changes to those policies. Doing so will facilitate best clinical practices in terms of pain management and will reduce the chances for practice disruption through inadvertent intrusion by the legal system.

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Overview: A Capsule Summary of Steps You Can Take Today

This book and the updated resources on the FSMB's website offer a pragmatic framework for treating pain with compassion and vigilance. I hope it adds to your confidence to practice medicine by seeking to cure when possible, but to always treat suffering.

The steps that are stressed in these chapters should not impose new burdens, because the approaches, procedures, and mindset advocated in the *Model Policy* articulate the standards that are essential components of sound medical care that physicians strive to achieve every day. Putting the *Model Policy* to work, therefore, is more a matter of reframing one's approach than adopting an entirely new way of practice. However, many of these steps will be difficult to attain on a daily basis in a busy general practice without increasing your knowledge base about pain management and developing simple, skills, tools, and procedures that will expedite the process.

This will not be an onerous addition to your work if you prepare in advance for the education and monitoring needs of your patients who require controlled substances and refine your general knowledge base and skills around assessment and documentation. And once accomplished, the principles and practices discussed in this book will enhance your clinical operation well beyond prescribing controlled substances.

Below is a capsule summary of the steps you can take right now to integrate the tenets of the *Model Policy* into your day-to-day practice:

1. Patient Evaluation

- Make time to listen carefully to patients in pain.
- Use a reflective listening approach.
- Remain mindful of the need for suspicion without a rush to judgment.
- Look for signs of abuse, but recognize the complexities of presentation and the possibilities of pseudoaddiction.
- Remember that not treating pain is often not a “safe” option.

2. Treatment Plan

- Use a function-based paradigm at diagnosis and follow through with a function-based treatment plan.
- Develop a list of functional losses and gains that will be impacted by care, then track and modify them throughout care.
- Simply “feeling better,” without improving functioning in some aspect of an individual’s life, may not reflect improvement in quality of life.
- Modest reductions in pain score may actually be extremely significant in terms of reclaimed function.

3. Informed Consent and Agreement for Treatment

- Patients must fully understand the potential risks and benefits of any procedure or treatment to be truly “informed” as required by both law and medical ethics.
- Regardless of whether or not you are prescribing a controlled substance, there are tangible advantages to incor-

porating risk education information into a clear and transparent process.

- Prepare the educational materials and other documents that you will need in advance and develop in advance an efficient process for implementing these steps for all of your patients—much of which can take place outside of your exam room. (See Appendix A for online educational resources you can download and use in your practice.)
- A written agreement/informed consent process can help addresses the key points of the *Model Policy* (Go to www.fsbm.org/pain for more information about agreements and sample agreements that you can adapt to the needs of your patients and practice.)

4. Periodic Review

- As in all treatments, including those involving controlled substances, physicians must closely attend to treatment outcomes and be alert to a wide range of potential adverse effects.
- Monitoring progress toward a set of functional goals requires a means of measuring progress (or lack thereof), which must be clearly documented from the start of treatment.
- The responsibility of attaining treatment goals and presenting supporting evidence lies with the patient.
- Assess functional goals and move the “goalposts” as needed.

5. Referral and Patient Management

- Build a network of clinical experts to whom you can turn for specialized needs.

- Be clear with yourself about the breadth and depth of your expertise, and don't hesitate to refer patients at the earliest signs they may need help.
- Remember that patients in pain can appear "difficult," but that the most "difficult" patients are often the ones who most desperately need your help.

6. Documentation

- Documentation is an essential component at every step of the process of delivering pain care.
- Document assessments, treatment agreements, education; action plans, and patient monitoring activities.
- Be clear about why you are taking risks and your plan for risk management. Transparency as to your reasoning about risk management decision-making is a critical component of documentation.
- Include enough specific information that a person reading the document understands the implications of exam results or other details of the history or treatment plan.

7. Compliance With Controlled Substance Laws and Regulations

- Know your state regulations on controlled substances and adhere strictly to them.
- Be familiar with and adhere to all relevant Federal regulations.
- Access to relevant state and federal laws is available through the Federation of State Medical Boards website: www.fsmb.org/pain.

Conclusion: Balancing Vigilance and Compassion

As the preceding chapters demonstrate, the FSMB *Model Policy* focuses on process-oriented aspects of patient care, leaving selection of drug, dose, duration, etc. well within the bounds of each physician's clinical judgment. These principles are presented as a basic framework for an organized, systematic medical practice. They offer substantial latitude and flexibility, allowing practitioners to deviate from these steps if, in their reasoned judgment, it's in the best medical interest of a patient.

By incorporating this framework, you can take comfort in knowing that, although heightened concern about controlled substances may remain among clinicians and regulators, practicing in accord with the FSMB *Model Policy* squarely aligns you with adherence to basic tenants of well-established medical practices. Perhaps more important, adhering to the tenants of the *Model Policy* not only facilitates appropriate treatment of pain with controlled substances, but also supports a healthy overall practice.

That is the backdrop against which this book and the *Model Policy* were conceived: Delivering optimal care to patients in pain. The patient is the ultimate beneficiary of therapeutic pharmacovigilance. As we treat patients in pain, it is all too easy to lose sight of these goals, particularly in an atmosphere of legitimate concerns over abuse

and diversion. It is vitally important that the best interest of the patient and society always remain in the foreground.

As the FSMB *Model Policy* emphasizes, opioid analgesics are legitimate and effective agents for pain control. Nonetheless, they are not always indicated or appropriate. As always, clinicians must base their decisions to use or withhold opioids on a case-by-case risk/benefit analysis, keeping in mind that there are substantial risks associated with ignoring pain. As described in its introduction, the FSMB *Model Policy* is a tool that medical boards and other regulators use to assess whether your practice is within the standard of care. Thus, a practice consistent with the tenets of the *Model Policy* should be positively viewed by regulators. This may reduce the hesitation—or even paralysis—that some practitioners now feel about prescribing controlled substances.

The fundamental tenets of responsible opioid prescribing for pain—complete evaluation, balanced risk-management, and transparent documentation—are the pillars of any functional medical practice, particularly in pain management. In the often murky realm of pain assessment and treatment, trust and transparency are paramount within the therapeutic relationship. Therefore, I cleave to the Russian proverb that Ronald Reagan liked to quote: “Trust, but verify.” Maintaining clinical vigilance is critically important in all domains of medical practice and is particularly important for patients in pain who are at increased risk of a host of complex collateral consequences. These include an array of manifestations of physical as well as psychological deconditioning, such as fatigue, insomnia, depression, anxiety, and even suicide. Some patients may also be at risk for

addiction. By establishing a clear framework for assessing, treating, and tracking patients, we improve our odds of achieving an optimal therapeutic outcome.

The FSMB *Model Policy* does not set a standard of medical practice. These details of care require medical knowledge and information about a patient that can only be determined through the deliberate and individualized clinical judgment of the treating physician. Since few generalizable treatment algorithms exist, regulators should recognize—as I believe they do—that society is best served by prudent risk-conscious practitioners who apply their best judgment, based on individual characteristics that vary greatly from patient to patient.

Physicians are given great latitude in judgment when risks are managed with rational and systematic care. This involves treatment choices that are made with circumspect consideration of past and ongoing case details, a reasonable breadth of diagnostic expertise and treatment options, and vigilant attention to treatment goals and outcomes—all of which are clearly and transparently documented. With no single accepted method for comprehensive assessment and monitoring, physicians must use their knowledge and judgment to determine a best plan for each individual patient. This may include global policies and procedures applied to all patients in your practice, or used on a case-by-case basis. Just as in managing risk in any other treatment setting, the foundation for success rests on knowledge, concern, awareness, and proactive initiative. And as with all aspects of medical care, whenever risk is decreased, barriers to initiating interventions are lowered and chances for beneficial outcomes rise. Managing risks and benefits is

at the core of what we physicians do with all our patients; vigilance in pain management is nothing more or less than effective risk management.

Obviously, physicians must remain current not only with new developments in medicine, but also with related changes in state and federal laws. To this end, the Federation of State Medical Boards is posting updated information relevant to opioid prescribers on its website at www.fsmb.org/pain. Amongst many valuable resources, this site includes:

- Updated prescribing standards for each state;
- Links to updated information about the DEA's requirements for prescribing controlled substances; and
- Links to SAMHSA, FDA, and other government websites where you can find updated information and warnings about prescription medications.

In addition to providing resources for pharmacovigilant practice, the FSMB site also offers links to useful online pain management resources. Though most of us are called upon to treat patients in pain, few physicians have been given a full set of resources to respond to these patients' special needs. I believe that the reason many doctors resist treating pain is not that they lack compassion, are unwilling to engage with difficult cases, or that they shy away from potential legal and regulatory hassles. It is because, in the past, medicine has not made pain care a priority, and consequently most physicians are not well-trained or well-equipped to manage pain.

Pain Medicine is a young discipline that is still barely represented in medical school curricula or residency pro-

grams. Continuing medical education in pain management is largely sponsored by industry, and its quality and practicality often is hit-or-miss. We are unlikely to succeed in reversing the problem of undertreated pain without increasing education and support for physicians at all levels of training—not just in pain management, but also in drug abuse, addiction, and rational approaches to a functional practice that balances compassionate care with appropriate pharmacovigilance.

Meanwhile, the science and technology of pain medicine is expanding at a rapid rate, encompassing pain physiology, medications, procedures, devices, and other therapies. Each of us has a responsibility to attain a basic working understanding of pain management, and if one chooses to prescribe opioids or other controlled substances, a clear understanding of safe and effective prescribing practices.

Obviously, the content of this book cannot substitute for the commitment to relieve suffering. The tenets of the FSMB *Model Policy*, or any consensus practice guidelines, are only useful in service to conscientious pain management. There is no debate among public health experts about the undertreatment of pain, which has been recognized as a public health crisis for decades. The cost of undertreated pain in dollars is astronomical, but the cost in human suffering is immeasurable. Turning away from patients in pain simply is not an option.

Appendix A: Resources for Pharmacovigilance and Pain Management

The FSMB's website at www.fsmb.org/pain can serve as a first stop destination for up-to-date resources for pharmacovigilance in pain management. On this site you'll find:

- The FSMB *Model Policy* for the Use of Controlled Substances for the Treatment of Pain
- Updated state-by-state prescribing guidelines for the use of controlled substances, as well as other relevant state-based regulations
- Links to websites at the Substance Abuse and Mental health Services Administration, Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA) where you'll find updated information about drug safety and pharmacovigilance

In addition to staying current with state and federal regulations governing controlled substance prescribing, it's also important to stay abreast of safe and effective pain management. As with any job, effectively treating patients in chronic pain is easier when you use the right tools. I'm talking here about assessment instruments, scales for quantifying pain, intake questionnaires, patient education handouts, and well-crafted doctor/patient agreements. Many versions of these kinds of tools are available for downloading from the

Responsible Opioid Prescribing: A Physician's Guide

Internet. Below I've listed the sites I can recommend to you—and I've marked my most highly recommended sites with a . I've also listed some books about pain and pain management that you or your patients might find helpful.

- 1. Federal Government Resources**
- 2. Medical Specialty Society Sites**
- 3. Nonprofit Pain Organizations (and other sites of interest to medical professionals)**
- 4. Treatment Guidelines**
- 5. Pain and Function Assessment Tools**
- 6. Commercially Sponsored Sites Offering Useful Clinical Tools**
- 7. Medical Journals Focusing on Pain**
- 8. Sites with Educational Information for Consumers**
- 9. Professional and Patient Sites by Disorder**
- 10. Pain-Related Books**

1. FEDERAL GOVERNMENT RESOURCES

Substance Abuse and Mental Health Services

Administration (SAMHSA): www.samhsa.gov/

- National Survey on Drug Use and Health: Nonmedical Users of Pain Relievers, Characteristics of Recent Initiates: www.oas.samhsa.gov/2k6/pain/pain.cfm
- NonMedical Use of Pain Relievers: www.oas.samhsa.gov/subState2k6/agePain.htm
- Directory of drug and alcohol abuse treatment programs: <http://findtreatment.samhsa.gov>

Drug Enforcement Administration (DEA):

www.usdoj.gov/dea/index.htm

- Drug Scheduling: www.usdoj.gov/dea/pubs/scheduling.html
- Drug Information: www.usdoj.gov/dea/concern/concern.htm
- Diversion Control: www.deadiversion.usdoj.gov/
- DEA Practitioners Manual: www.deadiversion.usdoj.gov/pubs/manuals/pract/index.html
- Survey of State Prescription Monitoring Programs: www.deadiversion.usdoj.gov/pubs/program/ijis_pmix_survey20070204.pdf

The U.S. Food and Drug Administration (FDA): www.fda.gov

The National Institute on Drug Abuse (NIDA):

www.drugabuse.gov

- Prescription Drug Abuse Chart: www.drugabuse.gov/DrugPages/PrescripDrugsChart.html

The Office of National Drug Control Policy:

www.whitehousedrugpolicy.gov

- The President's National Drug Control Strategy: www.whitehousedrugpolicy.gov/publications/policy/ndcs07/

2. MEDICAL SPECIALTY SOCIETY SITES

American Academy of Orofacial Pain

www.aaop.org

19 Mantua Road

Mount Royal, NJ 08061

856-423-3629

Fax: 856-423-3420

★ **The American Academy of Pain Medicine**

www.painmed.org
4700 W. Lake Ave.
Glenview, IL 60025
847-375-4731
Fax: 847-375-4777

American Medical Association

www.ama-assn.org
515 N. State Street
Chicago, IL 60610
800-621-8335

★ **American Pain Society (APS)**

www.ampainsoc.org
4700 W. Lake Ave.
Glenview, IL 60025
847-375-4715
Fax: 877-734-8758

A multidisciplinary organization of basic and clinical scientists, practicing clinicians, policy analysts, and others. The mission of the APS is to advance pain-related research, education, treatment, and professional practice.

American Psychological Association

www.apa.org
750 First Street, NE
Washington, DC 20002
800-374-2721
Offers referrals, assistance, and resources for coping with the psychological aspects of trauma and terrorism.

American Society of Addiction Medicine

www.asam.org

Email@asam.org

4601 North Park Ave, Arcade Suite 101

Chevy Chase, MD 20815

301-656-3920

Fax: 301-656-3815

American Society for Pain Management Nursing

www.aspmn.org

7794 Grow Drive

Pensacola, FL 32514

888-34-ASPMN (342-7766)

Fax: 850-484-8762

3. NONPROFIT PAIN ORGANIZATIONS (and other sites of interest to medical professionals)

Alliance of State Pain Initiatives

www.aspi.wisc.edu

1300 University Avenue, Room 4720

Madison, WI 53706

608-265-4013

Fax: 608-265-4014

American Council for Headache Education

www.achenet.org

19 Mantua Road

Mt. Royal, NJ 08061

856-423-0258, or 800-255-ACHE (255-2243)

Fax: 856-423-0082

★ **AMA Pain Management: The Online Series**

www.ama-cmeonline.com

Web-based Continuing Medical Education program on pain management from the American Medical Association

Arthritis Foundation

www.arthritis.org

help@arthritis.org

1330 West Peachtree Street

Suite 100

Atlanta, GA 30309

800-568-4045, or 404-872-7100, or 404-965-7888

Fax: 404-872-0457

City of Hope Pain/Palliative Care Resource Center

www.cityofhope.org/prc/

City of Hope Pain/Palliative Care Resource Center

1500 East Duarte Road

Duarte, CA 91010

A clearinghouse of resources to enable individuals and institutions to improve the quality of pain management delivery.

The Cochrane Collaboration

www.cochrane.org

A wide-ranging collection of evidence-based reviews including topic in pain management.

Fibromyalgia Network

www.fmnetnews.com

Educational materials on fibromyalgia syndrome (FMS) and chronic fatigue syndrome (CFS).

International Association for the Study of Pain

www.iasp-pain.org

The leading international society of multidisciplinary pain professionals; its website offers many valuable resources for professionals.

National Consensus Project for Quality Palliative Care

www.nationalconsensusproject.org

A collaborative project of the American Academy of Hospice and Palliative Medicine, Hospice and Palliative Nurses Association, and the National Hospice and Palliative Care Organization to promote the implementation of Clinical Practice Guidelines for new and existing palliative care services.

National Institute of Dental and Craniofacial Research (NIDCR)

www.nidcr.nih.gov

nidcrinfo@mail.nih.gov

National Institutes of Health, DHHS

31 Center Drive, Room 5B-55

Bethesda, MD 20892

National Headache Foundation

www.headaches.org

info@headaches.org

312-274-2650, or 888-NHF-5552 (643-5552)

Fax: 312-640-9049

820 N. Orleans

Suite 217

Chicago, IL 60610-3132

UCLA History of Pain Project: The John C. Liebskind History of Pain Collection

www.library.ucla.edu/libraries/biomed/his/pain.html

The most extensive resource on the history of Pain Medicine.

★ Pain and Policy Studies Group

www.medsch.wisc.edu/painpolicy/

The leading resource for pain-related public policy and legislative issues.

4. TREATMENT CONSENSUS STATEMENTS, GUIDES, AND GUIDELINES

★ Model Policy for the Use of Controlled Substances for the Treatment of Pain

www.fsmb.org/grpol_policydocs.html

Federation of State Medical Boards

Offers clear guidance on standards for controlled substance prescribing.

The Use of Opioids for the Treatment of Chronic Pain

www.asam.org

www.painmed.org

Consensus statement by American Pain Society, American Academy of Pain Medicine, American Society of Addiction Medicine.

JCAHO Pain Management Standards

www.jcrinc.com

Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction

www.kap.samhsa.gov/products/tools/keys/pdfs/KK_40.pdf
Substance Abuse and Mental Health Services Administration (SAMHSA)

World Health Organization Cancer Pain Relief: Guide to Opioid Availability

www.who.int/cancer/publications/en/
World Health Organization

Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain

www.ampainsoc.org
American Pain Society

Definitions Related to the Use of Opioids for the Treatment of Pain

www.asam.org/pain/definitions2.pdf
American Academy of Pain Medicine, American Pain Society, American Society of Addiction Medicine

5. PAIN AND FUNCTION ASSESSMENT TOOLS

The assessment tools below are widely available online for downloading in various formats, including at several of the commercially sponsored sites described in the following section.

Initial Pain Assessment Tool

www3.mdanderson.org/depts/prg/bpi.htm
A charting form that can be used on the patient's initial admission to document location, intensity, quality of pain, and relief.

Brief Pain Inventory (BPI)

www.cityofhope.org/prc/pdf/BPI%20Short%20Version.pdf

A brief, simple, and easy to use tool for the assessment of pain in both clinical and research settings. The BPI uses simple numeric rating scales from 0 to 10 that are easy to understand and easy to translate into other languages. It is a well-validated instrument to measure pain intensity, functionality, and the impact of pain on one's life in the past 24 hours and within the past week.

McGill Pain Questionnaire

www.cityofhope.org/prc/pdf/McGill%20Pain%20Questionnaire.pdf

A 20-item scale that allows patients to articulate ranges of pain sensation, both internal and external.

Visual Analog Scale

www.ndhcri.org/pain/Tools/Visual_Analog_Pain_Scale.pdf

A linear scale from Worst Imaginable Pain to No Pain. Patients place a mark along the line to indicate their current pain level.

Wong-Baker FACES Pain Rating Scale

www3.us.elsevierhealth.com/WOW/

A scale that employs pictures of faces, ranging from happy to sad to assess pain in children; while designed to assess pain in children; it is also used to assess pain in adults.

6. COMMERCIAL SPONSORED SITES OFFERING USEFUL CLINICAL TOOLS

Many of the clinical tools described in this book are available at one or more of these commercially sponsored pain management sites.

Emerging Solutions in Pain Management

www.emergingsolutionsinpain.com

A diverse collection of practical tools and resources for clinical pain management.

Sponsored by Cephalon.

National Pain Education Council™ (NPEC)

www.npecweb.org

A compendium of online CME, clinical tools, and other pain management reference sources.

Supported by Ortho-McNeil.

Pain.com

www.pain.com

Clearinghouse for chronic pain management resources, including breakthrough pain and cancer pain.

Sponsored by Purdue Pharma L.P. and Cephalon.

PainBalance.org

www.PainBalance.org

An educational site featuring physician and patient resources that emphasize the balance between safe and effective pain management and opioid abuse.

Sponsored by Alpharma Pharmaceuticals LLC.

PainEDU.org

www.painedu.org

An online resource for clinically relevant information about pain assessment and management.

Supported by Endo.

Partners Against Pain

www.partnersagainstpain.com

An informational site for patients, health professionals, and physicians.

Supported by Purdue Pharma L.P.

Legal Side of Pain

www.legalsideofpain.com

Free and subscription based information on legal issues related to pain.

7. MEDICAL JOURNALS FOCUSING ON PAIN

Headache: The Journal of Head and Face Pain

American Headache Society

www.blackwellpublishing.com/journal.asp?ref=0017-8748

Journal of Pain

American Pain Society

<http://journals.elsevierhealth.com/periodicals/yjpai>

Journal of Pain and Symptom Management Pain

www.elsevier.com/homepage/sah/pain/menu.html

Journal of Pain & Palliative Care Pharmacotherapy

www.haworthpress.com/store/product.asp?sku=J354

Pain

International Association for the Study of Pain

www.sciencedirect.com/pain

Pain Medicine

American Academy of Pain Medicine

www.blackwellpublishing.com/journal.asp?ref=1526-2375&site=1

8. SITES WITH EDUCATIONAL INFORMATION FOR CONSUMERS

★ American Pain Foundation

www.painfoundation.org

info@painfoundation.org

201 North Charles Street, Suite 710

Baltimore, MD 21201-4111

888-615-PAIN (7246)

Fax: 410-385-1832

An excellent source for patient information and advocacy with extensive links to further information as well as monitored chat rooms for consumers.

★ National Pain Foundation (NPF)

www.nationalpainfoundation.org

aardrup@nationalpainfoundation.org

300 E Hampden Avenue, Suite 100

Englewood, CO 80113

A comprehensive online education and support community for pain patients and their families.

9. PROFESSIONAL AND PATIENT SITES BY DISORDER

ADDICTION

American Society of Addiction Medicine (ASAM)

www.asam.org/

National Institute on Drug Abuse

www.nida.nih.gov

ARTHRITIS

Arthritis Foundation

www.arthritis.org

Medical College of Wisconsin/Arthritis

healthlink.mcw.edu/arthritiss/

Mayo Clinic Arthritis Center

www.mayoclinic.com/health/arthritiss/AR99999

BACK AND SPINE PAIN

Spine Health

www.spine-health.com

Spine Universe

www.spineuniverse.com

CANCER PAIN

American Cancer Society

www.cancer.org

Cancer Pain Control:

www.WHOcancerpain.wisc.edu

The Cancer Pain Education Resource (CAPER)

www.caper.tufts.edu

City of Hope Pain/Palliative Care Resource Center

www.cityofhope.org/prc

FIBROMYALGIA PAIN

The American Fibromyalgia Syndrome Association

www.afsafund.org

Fibromyalgia Network

www.fmnetnews.com

National Fibromyalgia Association

<http://fmaware.org>

HEADACHE PAIN

National Headache Foundation

www.headaches.org

American Council for Headache Education

www.achenet.org

TMJ Tutorial

www.rad.washington.edu/anatomy/modules/TMJ/TMJ.html

**COMPLEX REGIONAL PAIN SYNDROME (CRPS) PAIN
INTERNET RESOURCES**

**Reflex Sympathetic Dystrophy Syndrome Association
of America**

www.rsds.org

American RSDHope Group

www.rsdhope.org

NINDS Complex Regional Pain Syndrome Information Page

from the National Institute of Neurological Disorders and Stroke

www.ninds.nih.gov/disorders/reflex_sympathetic_dystrophy/reflex_sympathetic_dystrophy.htm

PEDIATRIC PAIN

American Academy of Pediatrics

www.aap.org

KidsHealth

www.kidsheath.org

Pediatric Pain—Science Helping Children

www.dal.ca/~pedpain/pedpain.html

10. PAIN-RELATED BOOKS

(available at amazon.com and other online bookstores)

The Body in Pain: The Making and Unmaking of the World

Elaine Scarry (Oxford University Press 1985).

Cancer Pain Relief

International Association for the Study of Pain; World Health Organization, (World Health Organization 1986).

Cancer Pain Relief and Palliative Care: Report of a WHO Expert Committee, WHO Technical Report Series 804

World Health Organization (World Health Organization 1990).

Core Curriculum for Professional Education in Pain

International Association for the Study of Pain, Task Force on Professional Education, (IASP Publications 1991).

The Culture of Pain

David B. Morris (University of California Press 1993).

Dying Well: Peace and Possibilities at the End of Life

Ira Byock (Riverhead 1998).

Full Catastrophe Living: Using the Wisdom of Your Body and Mind to Face Stress, Pain, and Illness

Jon Kabat-Zinn (Delta 1990).

Handbook of Cancer Pain Management 3rd Edition

Weissman, et al. (Wisconsin Pain Initiative 1992).

How We Die: Reflections on Life's Final Chapter

Sherwin B. Nuland (Vintage 1995).

The Illness Narratives: Suffering, Healing, and the Human Condition

A. Kleinman (Basic Books 1988).

Managing Pain Before It Manages You

Margaret A. Caudill (Guilford Press 2001).

Mastering Pain: A Twelve-Step Program for Coping With Chronic Pain

Richard A. Sternbach (Putnam 1987).

Natural Pain Relief: A Practical Handbook for Self-Help

Jan Sadler, Patrick Wall (C.W. Daniel Company 2004).

Nature of Suffering and the Goals of Medicine

Eric J. Cassell (Oxford University Press, USA 2004).

On Death and Dying

Elisabeth Kubler-Ross (Scribner 1997).

Pain and Suffering

William K. Livingston, Howard L. Fields (IASP Press 1998).

Phantoms in the Brain: Probing the Mysteries of the Human Mind

V.S. Ramachandran, Sandra Blakeslee (Harper Perennial 1999).

Principles & Practice of Pain Management

Carol A Warfield, Zahid H. Bajwa (McGraw-Hill Professional Publishing; 2nd edition 2003).

Suffering

Betty Ferrell, Editor (Jones & Bartlett Publishers 1996).

The War on Pain

Scott Fishman (Harper Paperbacks 2001).

When Bad Things Happen to Good People

Harold S. Kushner (Anchor 2004).

Wherever You Go, There You Are: Mindfulness Meditation in Everyday Life

Jon Kabat-Zinn (Hyperion 2004).

Appendix B:

Model Policy for the Use of Controlled Substances for the Treatment of Pain

**Federation of State Medical Boards
of the United States, Inc.**

Introduction

The Federation of State Medical Boards (the Federation) is committed to assisting state medical boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the Federation undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policy encouraging adequate treatment, including use of opioids when appropriate for patients with pain. The Federation thanks the Robert Wood Johnson Foundation for awarding a grant in support of the original project, and the American Academy of Pain Medicine, the American Pain Society, the American Society of Law, Medicine, & Ethics, and the University of Wisconsin Pain & Policy Studies Group for their contributions.

Since adoption in April 1998, the *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory

agencies, and practicing physicians and other health care providers. The *Model Guidelines* have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted pain policy using all or part of the *Model Guidelines*.¹ Despite increasing concern in recent years regarding the abuse and diversion of controlled substances, pain policies have improved due to the efforts of medical, pharmacy, and nursing regulatory boards committed to improving the quality of and access to appropriate pain care.

Notwithstanding progress to date in establishing state pain policies recognizing the legitimate uses of opioid analgesics, there is a significant body of evidence suggesting that both acute and chronic pain continue to be undertreated. Many terminally ill patients unnecessarily experience moderate to severe pain in the last weeks of life.² The undertreatment of pain is recognized as a serious public health problem that results in a decrease in patients' functional status and quality of life and may be attributed to a myriad of social, economic, political, legal and educational factors, including inconsistencies and restrictions in state pain policies.³ Circumstances that contribute to the prevalence of undertreated pain include: (1) lack of knowledge of medical standards, current research, and clinical guidelines for appropriate pain treatment; (2) the perception that prescribing adequate amounts of controlled substances will result in unnecessary scrutiny by regulatory authorities; (3) misunderstanding of

¹ As of January 2004, 22 of 70 state medical boards have policy, rules, regulations or statutes reflecting the Federation's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* and two (2) states have formally endorsed the *Model Guidelines*.

² SUPPORT Study Principal Investigators. A controlled trial to improve care for seriously ill hospitalized patients: *JAMA*, 274(20) (1995): p. 1591-1598.

³ A.M. Gilson, D.E. Joranson, and M.A. Mauer, Improving Medical Board Policies: Influence of a Model, *J. of Law, Medicine, and Ethics*, 31 (2003): p. 128.

addiction and dependence; and (4) lack of understanding of regulatory policies and processes. Adding to this problem is the reality that the successful implementation of state medical board pain policy varies among jurisdictions.

In April 2003, the Federation membership called for an update to its *Model Guidelines* to assure currency and adequate attention to the undertreatment of pain. The goal of the revised *Model Policy* is to provide state medical boards with an updated template regarding the appropriate management of pain in compliance with applicable state and federal laws and regulations. The revised policy notes that the state medical board will consider inappropriate treatment, including the undertreatment of pain, a departure from an acceptable standard of practice. The title of the policy has been changed from *Model Guidelines* to *Model Policy* to better reflect the practical use of the document.

The *Model Policy* is designed to communicate certain messages to licensees: that the state medical board views pain management to be an important and integral to the practice of medicine; that opioid analgesics may be necessary for the relief of pain; that the use of opioids for other than legitimate medical purposes poses a threat to the individual and society; that physicians have a responsibility to minimize the potential for the abuse and diversion of controlled substances; and that physicians will not be sanctioned solely for prescribing opioid analgesics for legitimate medical purposes. In addition, this policy is not meant to constrain or dictate medical decision-making.

Through this initiative, the Federation aims to achieve more consistent policy in promotion of adequate pain management and education of the medical community about treating pain within the bounds of professional practice and without fear of regulatory scrutiny. In promulgating this *Model Policy*, the Federation strives to encourage the legitimate medical uses of controlled substances for the treatment of pain while stressing

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the need to safeguard against abuse and diversion.

State medical boards are encouraged, in cooperation with their state's attorney general, to evaluate their state pain policies, rules, and regulations to identify any regulatory restrictions or barriers that may impede the effective use of opioids to relieve pain. Accordingly, this *Model Policy* has been revised to emphasize the professional and ethical responsibility of the physician to assess patients' pain and update references and definitions of key terms used in pain management.

The *Model Policy* is not intended to establish clinical practice guidelines nor is it intended to be inconsistent with controlled substance laws and regulations.

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Section I: Preamble

The (name of board) recognizes that principles of quality medical practice dictate that the people of the State of (name of state) have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity and costs associated with untreated or inappropriately treated pain. For the purposes of this policy, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

The diagnosis and treatment of pain is integral to the practice of medicine. The Board encourages physicians to view pain management as a part of quality medical practice for all patients with pain, acute or chronic, and it is especially urgent for patients who experience pain as a result of terminal illness. All physicians should become knowledgeable about assessing

patients' pain and effective methods of pain treatment, as well as statutory requirements for prescribing controlled substances. Accordingly, this policy has been developed to clarify the Board's position on pain control, particularly as related to the use of controlled substances, to alleviate physician uncertainty and to encourage better pain management.

Inappropriate pain treatment may result from physicians' lack of knowledge about pain management. Fears of investigation or sanction by federal, state and local agencies may also result in inappropriate treatment of pain. Appropriate pain management is the treating physician's responsibility. As such, the Board will consider the inappropriate treatment of pain to be a departure from standards of practice and will investigate such allegations, recognizing that some types of pain cannot be completely relieved, and taking into account whether the treatment is appropriate for the diagnosis.

The Board recognizes that controlled substances including opioid analgesics may be essential in the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins. The Board will refer to current clinical practice guidelines and expert review in approaching cases involving management of pain. The medical management of pain should consider current clinical knowledge and scientific research and the use of pharmacologic and non-pharmacologic modalities according to the judgment of the physician. Pain should be assessed and treated promptly, and the quantity and frequency of doses should be adjusted according to the intensity, duration of the pain, and treatment outcomes. Physicians should recognize that tolerance and physical dependence are normal consequences of sustained use of opioid analgesics and are not the same as addiction.

The (name of board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The

Board recognizes that the use of opioid analgesics for other than legitimate medical purposes poses a threat to the individual and society and that the inappropriate prescribing of controlled substances, including opioid analgesics, may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board expects that physicians incorporate safeguards into their practices to minimize the potential for the abuse and diversion of controlled substances.

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice. The Board will consider prescribing, ordering, dispensing or administering controlled substances for pain to be for a legitimate medical purpose if based on sound clinical judgment. All such prescribing must be based on clear documentation of unrelieved pain. To be within the usual course of professional practice, a physician-patient relationship must exist and the prescribing should be based on a diagnosis and documentation of unrelieved pain. Compliance with applicable state or federal law is required.

The Board will judge the validity of the physician's treatment of the patient based on available documentation, rather than solely on the quantity and duration of medication administration. The goal is to control the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors.

Allegations of inappropriate pain management will be evaluated on an individual basis. The board will not take disciplinary action against a physician for deviating from this policy when contemporaneous medical records document reasonable cause for deviation. The physician's conduct will be evaluated to a great extent by the outcome of pain treatment, recognizing that

some types of pain cannot be completely relieved, and by taking into account whether the drug used is appropriate for the diagnosis, as well as improvement in patient functioning and/or quality of life.

Section II: Guidelines

The Board has adopted the following criteria when evaluating the physician's treatment of pain, including the use of controlled substances:

- 1. Evaluation of the Patient*—A medical history and physical examination must be obtained, evaluated, and documented in the medical record. The medical record should document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, and history of substance abuse. The medical record also should document the presence of one or more recognized medical indications for the use of a controlled substance.
- 2. Treatment Plan*—The written treatment plan should state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and should indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician should adjust drug therapy to the individual medical needs of each patient. Other treatment modalities or a rehabilitation program may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.
- 3. Informed Consent and Agreement for Treatment*—The physician should discuss the risks and benefits of the use of controlled substances with the patient, persons designated by the patient or with the patient's surrogate or guardian if the patient is without medical decision-making capacity. The patient should

receive prescriptions from one physician and one pharmacy whenever possible. If the patient is at high risk for medication abuse or has a history of substance abuse, the physician should consider the use of a written agreement between physician and patient outlining patient responsibilities, including

- a. urine/serum medication levels screening when requested;
- b. number and frequency of all prescription refills; and
- c. reasons for which drug therapy may be discontinued (e.g., violation of agreement).

4. Periodic Review—The physician should periodically review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health. Continuation or modification of controlled substances for pain management therapy depends on the physician's evaluation of progress toward treatment objectives. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Objective evidence of improved or diminished function should be monitored and information from family members or other caregivers should be considered in determining the patient's response to treatment. If the patient's progress is unsatisfactory, the physician should assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

5. Consultation—The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention should be given to those patients with pain who are at risk for medication misuse, abuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder may require extra care, monitoring, documentation and consultation with or referral to an expert in the management of such patients.

6. *Medical Records*—The physician should keep accurate and complete records to include

- a. the medical history and physical examination,
- b. diagnostic, therapeutic and laboratory results,
- c. evaluations and consultations,
- d. treatment objectives,
- e. discussion of risks and benefits,
- f. informed consent,
- g. treatments,
- h. medications (including date, type, dosage and quantity prescribed),
- i. instructions and agreements and
- j. periodic reviews.

Records should remain current and be maintained in an accessible manner and readily available for review.

7. *Compliance With Controlled Substances Laws and Regulations*—

To prescribe, dispense or administer controlled substances, the physician must be licensed in the state and comply with applicable federal and state regulations. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and (any relevant documents issued by the state medical board) for specific rules governing controlled substances as well as applicable state regulations.

Section III: Definitions

For the purposes of these guidelines, the following terms are defined as follows:

Acute Pain—Acute pain is the normal, predicted physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. It is generally time-limited.

Addiction—Addiction is a primary, chronic, neurobiologic disease, with genetic, psychosocial, and environmental factors

influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control over drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

Chronic Pain—Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury, or that may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over months or years.

Pain—An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Physical Dependence—Physical dependence is a state of adaptation that is manifested by drug class-specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and/or administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

Pseudoaddiction—The iatrogenic syndrome resulting from the misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are commonly seen with addiction. The relief seeking behaviors resolve upon institution of effective analgesic therapy.

Substance Abuse—Substance abuse is the use of any substance(s) for non-therapeutic purposes or use of medication for purposes other than those for which it is prescribed.

Tolerance—Tolerance is a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect, or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

About the Author

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Dr. Fishman is past president of the American Academy of Pain Medicine, is Vice Chairman of the board of directors for the American Pain Foundation, and has served on the board of directors for the American Pain Society. He has helped national and state legislatures with pain-related laws and consults to numerous government agencies and organizations, such as the Federation of State Medical Boards (FSMB), The Drug Enforcement Administration (DEA), and various state medical boards.